MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

OREGON HEALTH AUTHORITY

EVALUATION OF A SINGLE OR ALIGNED PREFERRED DRUG LIST

JULY 31, 2018

DEDICATED TO GOVERNMENT HEALTH PROGRAMS

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Executive Summary

The expenditure growth of prescription drugs has been an ongoing topic of concern for the last several years in all health care delivery systems and at all levels of government. Across all of the major sectors of health care spending, growth is anticipated to be the fastest for prescription drugs, averaging 6.3 percent for 2017 through 2026.[1] According to the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary, this growth is due, in part, to increases in drug pricing and utilization trends for costly specialty drugs. Although no consistent definition for specialty drugs exist, specialty drugs are generally those that are high in cost, require special handling, and need more intensive patient education regarding their use. In response to the various national prescription drug pricing concerns, the Trump administration has released "American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs".[2]

The ongoing expenditure growth of Medicaid spending for prescription drugs continues to be an area of great concern for Medicaid executive management, advisory bodies, coordinated care organizations (CCOs), and state legislators. State Medicaid programs continue to be innovative in developing mechanisms to ensure appropriate access to medically necessary pharmaceuticals, while working within budgetary limitations and ongoing enrollment expansion. The State of Oregon Medicaid program's pharmacy costs (net, after rebate) have increased by 9.1 percent from 2015 to 2016.[3] In response to managing this growth, the Oregon Health Policy Board (OHPB) has proposed exploration of a single or more aligned preferred drug list (PDL) approach. The PDL is a listing of drugs that represent a major component of the covered outpatient drugs available to Medicaid members. It was developed to better manage utilization and expenditures, taking into account clinical evidence, along with gross (before rebate) and net (after rebate) cost perspectives. This single or more aligned approach would require all enrolled Medicaid members to utilize all or a portion of the fee-for-service (FFS) PDL regardless of the delivery system they are enrolled in. It is important to note that the implementation of a single or aligned PDL approach would not result in carving out the prescription drug benefit from the CCO capitation payments.

The Oregon Health Authority (OHA) contracted with Myers and Stauffer, an accounting firm that provides consulting services to government programs and health care agencies (further described on page 44), to perform an evaluation of a single or aligned PDL approach. This evaluation involved the review and analysis of FFS and CCO pharmacy claims data, fiscal estimations, PDLs, related initiatives in other state Medicaid programs, stakeholder perspectives, ongoing meetings with OHA pharmacy leadership, operational realities, and other potential areas to explore related to controlling costs in the Oregon Medicaid pharmacy benefit.

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[1] CMS, Office of the Actuary, *National Health Expenditure Data: Projected*. www.CMS.gov (last updated Feb. 16, 2018, 11:11 a.m.), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.
[2] DEPT OF HEALTH AND HUMAN SVCS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.
[3] PRIMARYHEALTH ET AL., HOW A SINGLE STATE-MANDATED PREFERRED DRUG LIST WILL EXACERBATE THE OREGON MEDICAID PHARMACY FUNDING CRISIS (forthcoming) (on file with author).

Based upon the research conducted, Myers and Stauffer recommends OHPB and OHA consider and evaluate the following:

- *1) Consider pursuing an aligned PDL strategy and consistent pharmacy utilization management tools, including prior authorization (PA) criteria for the recommended 11 therapeutic classes or subset listed on page 36. The classes identified will not impact overall generic dispensing rates (GDRs) or negatively impact the relative drug mix. The estimated range of annual fiscal savings associated with these classes is $23 to $30 million state and federal dollars [S&F] with an estimated range of state share of $6.5 to $8.5 million.*
- *2) Develop a regulatory strategy and work plan for necessary legislative, rule making, procedural, or state plan amendment (SPA) activities related to an aligned PDL.*
- *3) Measure and regularly monitor fiscal performance for current and future therapeutic classes chosen for alignment.*
- *4) OHA, with input provided by Oregon State University (OSU) College of Pharmacy Drug Use Research and Management (DURM) Program, the Oregon Pharmacy and Therapeutics Committee (P&T) and the CCOs, should become the sole decision maker with regard to current and future therapeutic classes for PDL alignment. These therapeutic classes and related drugs will provide clear and meaningful net cost advantages for the state and federal taxpayers as the current approach has a certain degree of misaligned/competing financial interests.*
- *5) The CCOs should collaborate and actively provide collective input in the public P&T meeting process as a means to establish consistent utilization management tools and best practices between the FFS and CCO delivery systems.*
- *6) Examine, and as necessary, adjust CCO capitation rates to reflect additional expenditures they may experience due to the change to an aligned PDL. Particular attention should be directed at the transparency of the pharmacy encounter claims submitted by the CCOs, and ensure the understanding of the relationship of the encounter pharmacy payment amounts as related to the amounts actually paid to the pharmacies by their contracted pharmacy benefit managers (PBMs). In addition, any rebates or other remuneration obtained by the CCO or their contracted PBMs from drug manufacturers should be quantified for purposes of CCO contracting transparency and capitation rate setting.*
- *7) Alternatively, consider the use of an Administrative Services Organization model for aligned classes where OHA pays administrative fees to the CCOs for claims processing-related activities and reimburses the CCO directly for aligned therapeutic class pharmacy expenditures.*
- *8) Current mechanisms to review and utilize the various PDL formats are difficult and cumbersome. OHA, DURM, and the CCOs should collectively develop a user friendly consolidated PDL format with electronic search capabilities for the benefit of prescribers, pharmacies, program beneficiaries, and other interested parties. The resulting PDL format should also include utilization criteria and required PA forms associated with the*

specific drugs and/or therapeutic classes. Aligned therapeutic classes should be clearly noted.

- *9) Given the current and predicted expenditure growth of specialty pharmaceuticals, OHA, DURM, and the CCOs should collaboratively focus their collective expertise on implementing aligned utilization management strategies for specialty drugs. These specialty drugs include drugs dispensed by pharmacies and billed through pharmacy claims, as well as those purchased/administered by enrolled providers and billed through medical claims. The respective stakeholders should examine the role and feasibility of value-based purchasing (VBP) arrangements as a potential strategy to assist in managing specialty pharmaceutical spend.*
- *10) OHA should evaluate the "provider prevails" requirement established under ORS 414.334 to determine the current associated fiscal impact and determine if regulatory action should be pursued to revisit this requirement. OHA should consider optimizing the use of existing utilization management tools, such as step therapy, to maximize the use of preferred drugs providing the most value and ensure medical necessity of non-preferred drugs.*
- *11) Given the substantial national growth of 340B contract pharmacies and utilization of 340B drugs in recent years, OHA should carefully examine the drug utilization, expenditures, reimbursement amounts, and contractual requirements for 340B drugs in the CCO delivery systems. Currently, an OHA payment policy does not exist regarding CCO payment for covered outpatient drugs dispensed or administered by 340B covered entities and their contract pharmacies. This allows the CCOs to establish their own reimbursement policies for 340B dispensed drugs which may result in the CCO delivery systems paying at or near normal market reimbursement rates for these deeply discounted 340B drugs. OHA is not permitted to collect federal rebates when a 340B program drug has been dispensed; therefore, OHA may not only be grossly overpaying for these 340B drugs, but also sacrificing their ability to collect substantial federal rebates. This is an area that many states are actively evaluating and addressing through state policies or other regulatory channels. It has also gained attention at the federal level, as well as by the National Association of Medicaid Directors, and reports have been issued by both the Office of Inspector General and Government Accountability Office.*

It is important to note that these recommendations to OHPB and OHA represent the viewpoints of Myers and Stauffer and are specific to the State of Oregon Medicaid program. Many other aspects, such as regulatory changes, SPAs, and capitation rate analyses will require additional evaluation and research based upon the direction that is ultimately chosen.

Introduction, Background, and Purpose

In January 2018, OHPB adopted a charter to create a committee to focus on a variety of issues relating to the high costs of prescription drugs in Oregon. Subsequently, the Oregon Legislature passed, and Governor Brown signed HB 4005, which established a task force to examine prescription drug pricing transparency and related issues. This task force has been assigned to develop recommendations by November 2018 and is scheduled to continue through 2020. Based on the HB 4005 Task Force efforts, OHPB has elected to delay the formation of its own committee to best take advantage of, and not impede, the work of the Task Force.

Despite the OHPB decision to delay the formation of its committee, OHPB has directed OHA to continue analysis of pharmacy-related issues facing the Oregon Health Plan and the State in general. One specific idea OHPB has asked OHA to focus on is the ongoing assessment of a single statewide Medicaid PDL or aligning select therapeutic classes across CCO and FFS PDLs. The Oregon FFS PDL contains drugs prescribed for FFS members that have been identified as the most effective and safe drugs for the majority of patients, based on the information available by Oregon researchers and experts. Of the drugs recommended, only those representing the best value are included.[4]

This single PDL proposal would obligate the existing 15 CCOs to adhere to the same PDL as FFS Medicaid or could entail other efforts to align certain therapeutic classes of the CCOs' individual PDLs. During several dialogue exchanges and through public testimony, it is clear there is substantial concern with implementing changes to the PDL requirements without adequate evaluation of the potential savings, associated costs, and operational realities. A number of Oregon's 15 CCOs have signed a white paper that contends that a single PDL is not a viable option within the context of Oregon's Medicaid model that provides local control to the CCO.[5] The CCOs contend that their ability to manage their own PDLs gives them the flexibility they need to deliver under the coordinated care model. Due to the considerable expenditures associated with the pharmacy benefit and the implications to CCOs, OHA has contracted with Myers and Stauffer to perform an independent analysis that will result in recommendations to OHA for a PDL approach, with consideration of the CCOs and the Oregon Medicaid program as a whole.

Prior to delaying its committee, OHPB had directed OHA to explore the single PDL concept and provide an implementation plan for any recommendation by January 1, 2019. The board has not yet revised this timeline, but may update the committee charter and potential timeline after the completion and review of this report, and once additional feedback is available from stakeholders.

It should be noted that the Myers and Stauffer report and recommendations are an initial step in the overall process of reviewing this potential PDL policy change. Many other factors such as capitation rates, regulatory changes, contractual revisions, and consideration of necessary SPA changes will require additional evaluation and research.

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[4] Oregon Health Authority, *Oregon Health Plan Preferred Drug List*, OREGON.GOV, https://www.oregon.gov/OHA/HSD/OHP/Pages/PDL.aspx (last visited June 20, 2018).
[5] PRIMARYHEALTH ET AL., *supra* note 3

This report contains an analysis of policy options related to the PDL, including estimated potential savings associated with a select number of therapeutic classes, along with perspectives and positions of a single or aligned PDL approach. In addition, the report includes observations, considerations, and recommendations of a single or aligned PDL and other areas of the prescription drug benefit that should be evaluated. The PDL applies to claims primarily dispensed by pharmacy providers. As such, the data analysis evaluated utilization and expenditures for pharmacy claims only, and did not include claims for drugs purchased and billed by a provider through the medical benefit (physician administered/procedure coded drug claims). Performing an analysis on drugs billed through the medical benefit was not included in the scope of work. Currently, these drug claims are not subject to the PDL. Analysis of these claims would require additional time and effort due to the accuracy of submitted fields such as National Drug Code (NDC) and unit of measure (UOM), as well as the necessary related claim unit conversions. Myers and Stauffer is not an actuarial firm, and the evaluation of capitation rates was not within the scope of this project; therefore, we did not evaluate the potential impact to capitation rates and recommend that this exercise be performed by the State's actuarial services unit.

It is important to note that this PDL analysis report and the recommendations contained within are only applicable to the Oregon Medicaid program. Each Medicaid program should carefully evaluate their own program in the context of its specific structure, pharmacy program design, program goals, rebate programs, and federal matching considerations.

Prescription Drug Coverage and Reimbursement in Medicaid

Medicaid is a joint federal-state program that pays for medical assistance for individuals and families with low incomes and relatively few assets. Although pharmacy coverage is an optional benefit under federal Medicaid law, all states currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their state Medicaid programs.[6] Outpatient prescription drugs are typically those obtained only by prescription and dispensed by pharmacies, or drugs that are administered by a physician or other licensed health care professional in an outpatient setting. This does not include covered outpatient drugs provided and billed as part of other services or those provided during an inpatient hospital stay. Medicaid programs may also cover drugs sold without a prescription. These drugs are commonly referred to as over-the-counter (OTC) drugs, when prescribed by a physician or other authorized prescriber.

The amount Medicaid spends for a particular outpatient prescription drug reflects two components—the gross initial cost (made up of payment to a provider for the drug and the applicable dispensing fee) and the net cost of the drug after rebates (federal and/or supplemental) which Medicaid receives from drug manufacturers. States set pharmacy payment policy within federal guidelines and requirements; however, these policies must be approved by CMS through the SPA process. Additionally, a drug manufacturer must enter into a statutorily-defined rebate agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) in order for its products to be considered covered outpatient drugs by Medicaid.

[6] CMS, *Prescription Drugs*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/prescription-drugs/index.html (last visited May 31, 2018).

State Medicaid programs may utilize a single delivery system approach or a combination of delivery systems to provide prescription drug coverage to their enrolled beneficiaries. This may depend on a number of factors including, but not limited to, the population being served and/or characteristics of the geographic regions in the state.

In a FFS arrangement, the state enrolls and pays providers directly. The state typically hires vendors or performs some roles internally for various functions such as enrollment, claims processing, auditing, actuarial services, rate setting, medical policy, drug rebate administration, clinical services, and program consulting.

In a risk-based or capitated arrangement, the state procures managed care organizations (MCOs) or CCOs to contract and pay providers directly. This approach requires a SPA or waiver from CMS for implementation. The state pays these organizations through a calculated capitation rate which is required to be approved by CMS. Some services, such as prescription drugs (even specific subsets of drugs), dental, long-term care (LTC), or specific populations may be carved out of the capitation rate. The term "carved out" applies to services or populations that are not included in the capitation rate calculation and payment to the CCO, but paid for directly by the FFS delivery system.

The Medicaid and CHIP Managed Care Final Rule (CMS-2390-F)[7] provided updated regulations regarding the provision of health care services obtained through MCOs/CCOs. Among many other things, this rule specifies requirements for states and managed care plans that provide covered outpatient drugs under a capitated arrangement. Specifically, the rule addresses covered outpatient drug access in managed care and the application of federal rebates for covered outpatient drugs. Highlights of the rule related to covered outpatient drugs include the following:

- *Prescription drug coverage under MCOs/CCOs should demonstrate coverage consistent with the amount, duration, and scope as described by Medicaid FFS.*
- *MCOs/CCOs cannot have medical necessity criteria for prescription drugs that are more stringent than Medicaid FFS.*
- *MCOs/CCOs must provide coverage of covered outpatient drugs as specified in the contract.*
- *If a MCO/CCO is not contractually obligated to provide coverage of a particular covered outpatient drug, or class of drugs, the state is required to provide the covered outpatient drug through FFS that is consistent with the state plan.*
- *Each state may include covered outpatient drug coverage as part of the capitated contractual services or as a carve-out from the capitation rate calculations.*
- *A MCO/CCO that agrees to provide coverage of a subset of covered outpatient drugs under the contract with the state would need to provide coverage of every covered outpatient drug included in the subset if the manufacturer of those drugs entered into a rebate agreement.*

[7] CENTER FOR MEDICAID AND CHIP SERVICES, MEDICAID AND CHIP MANAGED CARE FINAL RULE (CMS-2390-F): COVERED OUTPATIENT DRUGS, https://www.medicaid.gov/medicaid/managed-care/downloads/mco-cod-presentation.pdf.

- *MCOs/CCOs have the flexibility to maintain their own PDLs or formularies and apply their own utilization management practices.*
- *It is incumbent upon the states and MCOs/CCOs to address formulary/PDL requirements in their contract documents. Each party must clearly understand their responsibilities and requirements when administering the Medicaid covered outpatient drug benefit.*
- *MCOs/CCOs need to ensure all covered outpatient drugs are covered unless the drug is contractually carved out of the pharmacy benefit.*
- *Payment to providers, PA requirements, drug utilization review programs and annual reports, access to pharmacy services, utilization data for rebate invoicing, and 340B claim identification.*

Overview of the Medicaid Drug Rebate Programs

Federal Drug Rebate Program

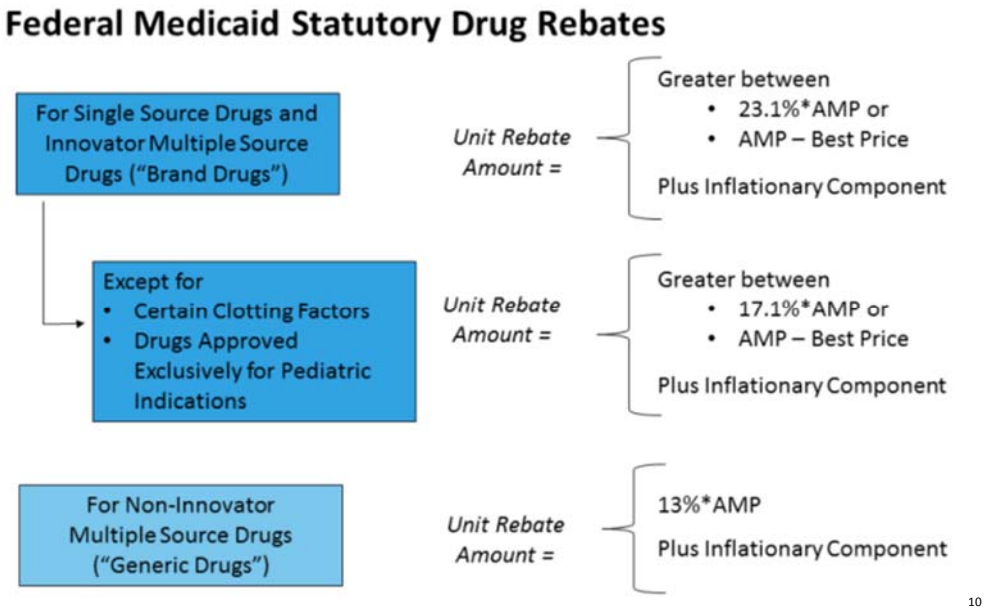
The Medicaid Drug Rebate Program (MDRP) was established by Congress (Title XIX of the Social Security Act) to ensure Medicaid receives a net price that is consistent with the lowest or best price for which manufacturers sell their drugs to other statutorily-defined payers. The state Medicaid agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for covered outpatient drugs. In exchange for the rebates, state Medicaid programs must generally cover a participating manufacturer's drugs, although, they may limit the use of some drugs through drug utilization management tools such as PDLs, medical necessity reviews, PA programs, or various other claim edits.

The rebates collected through the MDRP are shared between the federal government and states based on the state's current federal medical assistance percentage (FMAP). The FMAP can vary for different populations (i.e., traditional versus expansion) and for certain drugs (i.e., family planning and breast/cervical cancer). CMS calculates a unit rebate amount (URA) for each drug based on a defined formula for that category of drug and provides this URA to each state. The state then utilizes the CMS-supplied URA and the number of drug units that it paid for during the rebate period to calculate the rebate invoice amount. The state then submits a rebate invoice to the manufacturer each quarter. Rebates are invoiced and collected by the state through a process that is separate from their payments to pharmacies and other providers billing for covered outpatient drugs.

There are separate rebate formulas for brand drugs versus generic drugs.[8] The base brand rebate rate is 23.1 percent of the average manufacturer price (AMP) per unit. Rebates for certain clotting factor drugs and drugs approved exclusively for pediatric indications are 17.1 percent of the AMP per unit. The base generic rebate rate is 13 percent of the AMP per unit. The MDRP is intended to guarantee Medicaid the lowest net purchase price. The base rebate formula is supplemented by two additional provisions. The best price component assures that Medicaid pays no more than the lowest price available to any wholesaler, retailer, provider, or paying entity excluding certain government payers. In addition to the base rebate and best price provision, a

[8] CMS, *Medicaid Drug Rebate Program*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html (last visited May 31, 2018).

Consumer Price Index[9] (CPI) penalty is added to the calculation to protect against continual price increases that exceed the CPI for brand and generic drugs. Over recent years, brand name drug price increases have averaged eight to ten percent per year which emphasizes the importance of the CPI penalty. Due to the prescribed methodology used in calculating rebates, a manufacturer can control its rebate liability by virtue of their own pricing policies.



Beginning in 2010, the Affordable Care Act (ACA) extended the federal Medicaid drug rebates to prescriptions paid for by capitated Medicaid programs such as MCOs/CCOs. Previously, the federal rebates were only available for drugs paid for by the state on a FFS basis. In order to capture the rebates, states require MCOs/CCOs to submit their Medicaid drug utilization data to the state. The state then utilizes this information to invoice and collect rebates from the manufacturers. URAs, AMPs, and related calculations are proprietary and confidential.

Federal Offset of Rebates

The ACA increased the minimum rebate percentage for the vast majority of brand drugs from 15.1 percent to 23.1 percent of AMP; increased the rebate percentage for generic and other drugs from 11 percent to 13 percent of AMP; and changed the rebate calculation for line extension drugs. The ACA required states to remit the amounts attributable to these increased rebates to the federal government, and CMS gets both the federal and non-federal share of this rebate increase. In a State Medicaid Director letter, CMS further clarified that the offset would only occur on rebate dollars above that which would have been collected under the old rebate

[9] Bureau of Labor Statistics, *Table 24. Historical Consumer Price Index for All Urban Consumers (CPI-U): U.S. city average, all items,* https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-201801.pdf (last visited July 26, 2018)
[10] KATHERINE YOUNG & RACHEL GARFIELD, THE HENRY J. KAISER FAMILY FOUND., SNAPSHOTS OF RECENT STATE INITIATIVES IN MEDICAID PRESCRIPTION DRUG COST CONTROL 2 (2018), https://www.kff.org/medicaid/issue-brief/snapshots-of-recent-state-initiatives-in-medicaid-prescription-drug-cost-control/

formula before implementation of the ACA.[11] In other words, any additional rebate dollars obtained due to the increase in the minimum rebate percentage would be retained by the federal government at 100 percent.

Supplemental Drug Rebate Agreements

Supplemental drug rebates are collected in addition to the statutorily required rebates collected under the MDRP. A total of 47 Medicaid programs participate in supplemental rebate agreements.[12] Some states pursue supplemental rebate agreements on their own (single-state) while others join groups of states (multi-state pools) to increase negotiating power. States negotiate with manufacturers to obtain supplemental rebates within selected therapeutic classes. Manufacturers offer these supplemental rebates through a bidding process as an incentive to be selected for a state's PDL. Preferred drugs on the PDL are often not subject to PA, which results in increased utilization and market share of the preferred drugs over their non-preferred counterparts. It should be noted that a supplemental rebate offer from a manufacturer does not guarantee preferred placement on the PDL. The Oregon Medicaid PDL review process is founded upon evidence based review of safety and efficacy, utilization of experts, and transparency; net cost is a secondary consideration as noted on page 16.

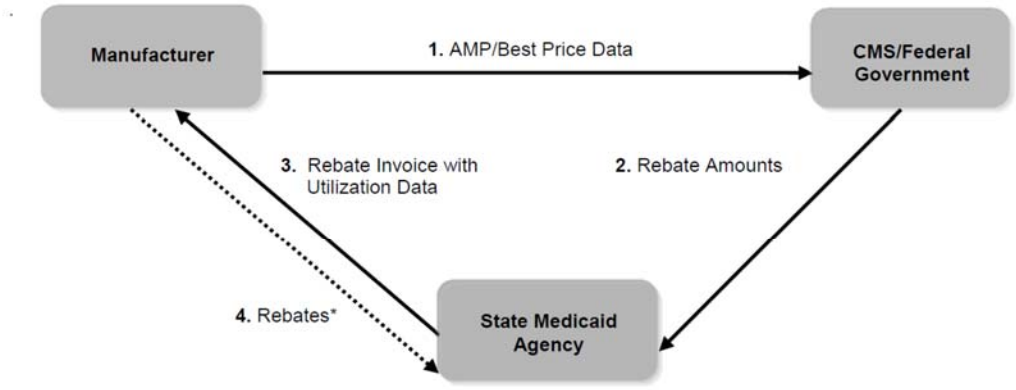
The supplemental rebate agreements between states and manufacturers are typically established through a guaranteed net unit price (GNUP) that the manufacturer will provide to the state. The supplemental rebate is generally calculated by comparing the federal rebate and GNUP to a benchmark price such as wholesale acquisition cost (WAC). GNUP contracts provide protection to state Medicaid programs from manufacturer pricing increases throughout the contract period. It is important to note that the federal rebate is typically responsible for the vast majority of total rebates collected. Often times, the federal rebate satisfies the GNUP contractual requirement by itself.

Per CMS State Release No. 176:

"Given that managed care organizations are often the primary mechanism for health care delivery in Medicaid, we urge that states consider negotiating supplemental rebates with manufacturers for some or all of their Medicaid managed care drug claims. Before negotiating supplemental rebates on managed care drug claims, states should determine the impact of their decision to collect supplemental rebates on their contracts with managed care organizations. States should determine if supplemental rebates in the managed care context will result in better patient outcomes and reduced costs to Medicaid overall. We urge states to work with their supplemental rebate contractors and Medicaid managed care organizations to better understand the impact of this policy. Alternatively, the state may want to align their fee-for-service preferred drug list and the state's Medicaid managed care organizations' formularies only for certain drug classes and collect supplemental rebates on those drugs dispensed to Medicaid managed care enrollees. A state that already has an approved CMS state plan that allows them to collect supplemental rebates on

[11] MEDICAID AND CHIP PAYMENT AND ACCESS COMM'N, MEDICAID PAYMENT FOR OUTPATIENT PRESCRIPTION DRUGS 7 (May 2018), https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.
[12] CMS, *Medicaid Pharmacy Supplemental Rebate Agreements (SRA)*, www.medicaid.gov, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf (last visited June 1, 2018).

Medicaid managed care claims will not need to change their approved state plan to implement such an approach."[13]



Source: CMS, *Medicaid Drug Rebate Data Guide for States*, section 1927(b) of the Act.
* With the exception of offset rebates (which States are prohibited from keeping), CMS and the States share Medicaid rebates on the basis of each State's FMAP.

Overall Rebate Impact

The impact of federal and supplemental rebates in Medicaid is substantial. These rebates guarantee that Medicaid programs obtain the lowest net price of any payer. In 2016, the average federal rebate was 53 percent off of gross pharmacy reimbursement. After inclusion of supplemental rebates, the average total discount ranged from 56 to 59 percent off of gross pharmacy reimbursement.[14] In other words, for every dollar spent in the Medicaid pharmacy program, an estimated 56 to 59 percent of that dollar comes back in the form of a federal and/or supplemental rebate, making Medicaid rebates a critical tool in managing pharmacy expenditures and their overall impact to state and federal Medicaid budgets.

Pharmacy Benefit Utilization Management Tools in Medicaid

Existing Medicaid regulations may limit the flexibility of a state Medicaid program to fully manage prescription drug coverage and spending. As previously stated, drug manufacturers are required to pay rebates to Medicaid; however, in return, the Medicaid program generally cannot exclude coverage of drugs produced by manufacturers enrolled in the MDRP. This includes coverage of new, high-cost drugs when they enter the market.[15] Unlike Medicaid, other payers have flexibility to make decisions regarding drug coverage and can use beneficiary cost sharing as a tool to drive volume to the most cost-effective options. Beneficiary cost sharing in Medicaid has limited impact in drug benefit design due to the nominal co-pay typically allowed under federal regulation

[13] Medicaid Drug Rebate Program Notice Release No. 176, CMS, Value-based Purchase Arrangements and Impact on Medicaid (July 14, 2016), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-176.pdf.
[14] MAGELLAN RX MGMT., MEDICAID PHARMACY TREND REPORT 7 (2nd ed. 2017), https://www1.magellanrx.com/media/671872/2017-mrx-medicaid-pharmacy-trend-report.pdf.
[15] Medicaid Drug Rebate Program Notice Release No. 185, CMS, State Medicaid Coverage of Drugs Approved by the FDA under Accelerated Approval Pathway (June 27, 2018), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-185.pdf

and described in State Medicaid Director Letter #06-015.[16,17] The nominal copay does not effectively incentivize the beneficiary to pursue lower cost alternatives.

While the statutory rebates help offset the expense of covered outpatient drugs, there are many utilization management tools that state Medicaid programs implement to effectively administer the pharmacy benefit. These tools provide a mechanism to control costs and assure appropriate medically necessary use of covered outpatient drugs. Some of the more common tools utilized by both FFS and CCO delivery systems include PDLs, PA programs, step therapy protocols, mandatory generic substitution, prospective and retrospective drug utilization review, and pharmacy claim edits related to quantity, days supply, age, gender, and diagnosis.

Prescription Drug Spending Trends in Medicaid

Medicaid spending on prescription drugs continues to be an important topic among state and federal policymakers. HHS recently published "American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs".[18] Medicaid prescription drug spending increased 24.6 percent in 2014, reaching its highest rate of growth since 1986, and slowed to 13.6 percent in 2015. The faster growth in 2014 was primarily due to increased spending for hepatitis C drugs. A higher amount of rebates helped temper the spending growth in 2015.[19] Slower enrollment growth and a decline in spending for hepatitis C drugs further reduced drug spending growth to 5.5 percent in 2016.[20] Even so, controlling prescription drug spending remains a focus for policymakers because prescription drugs are expected to experience the fastest average annual spending growth among major health care goods and services over the next 10 years.[21]

According to the *Magellan Rx Management Medicaid Pharmacy 2017 Second Edition Trend Report,* traditional (i.e., non-specialty) drug expenditure trend has been relatively flat on a gross cost per claim (-0.3 percent) and a net cost (post rebates) per claim (-5.1 percent). In contrast, the specialty drug expenditure trend experienced double-digit growth for the two-year study period (2015 through 2016) on both a gross cost per claim (22.8 percent) and a net cost per claim (20.5 percent).[22] *Table 1 and Table 2* on the following page illustrates these trends.

[16] State Medicaid Director Letter No. 06-015, Ctr. for Medicaid and State Operations, Ctrs. for Medicare & Medicaid Servs. (June 16, 2006), https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD061606.pdf
[17] VERNON K. SMITH ET AL., KAISER COMM'N ON MEDICAID AND THE UNINSURED, MANAGING MEDICAID PHARMACY BENEFITS: CURRENT ISSUES AND OPTIONS (SEPTEMBER 2011) https://www.kff.org/medicaid/report/managing-medicaid-pharmacy-benefits-current-issues-and-options/
[18] DEP'T OF HEALTH AND HUMAN SERVS., *supra* note 2.
[19] Anne B. Martin et al., *National Health Spending: Faster Growth in 2015 As Coverage Expands And Utilization Increases*, 36 HEALTH AFF. 166, 173 (2017), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2016.1330.
[20] Micah Hartman et al., *National Health Care Spending In 2016: Spending And Enrollment Growth Slow After Initial Coverage Expansions*, 37 HEALTH AFF. 150, 156 (2018), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.1299.
[21] Gigi A. Cuckler et al., *National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth*, 37 HEALTH AFF. 482, 484 (2018), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1655.
[22] MAGELLAN RX MGMT., *supra* note 14, at 4-5.

Table 1: Medicaid FFS Traditional Drug Spend

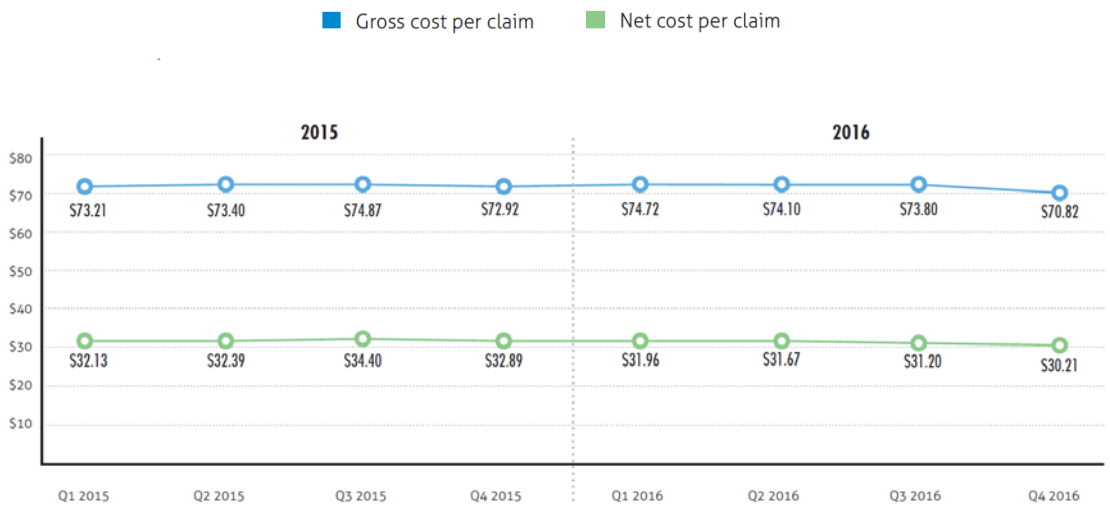
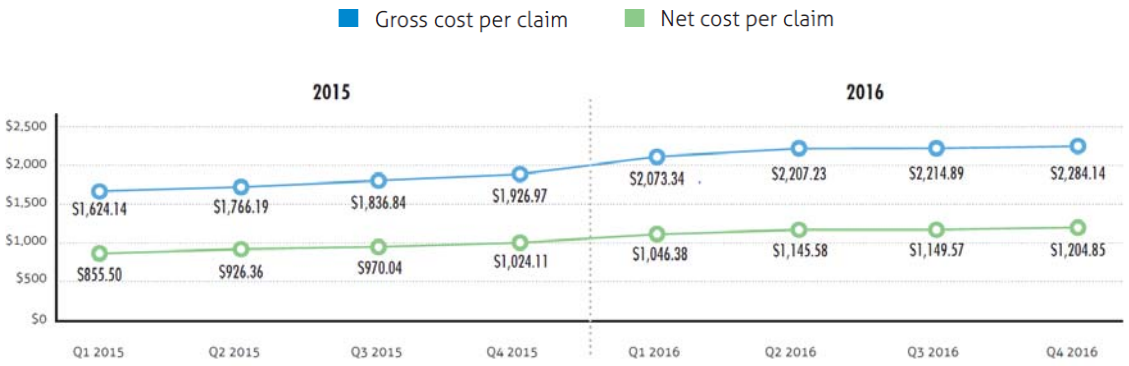


Table 2: Medicaid FFS Specialty Drug Spend



It is important to note that there is no universally accepted definition of specialty drugs. However, in the report, Magellan defines traditional and specialty drugs[23] in the following manner:

Traditional: therapeutic classes that have a lower cost per claim and a traditional route of administration, such as oral (tablets, capsules, liquids) or inhaled drugs.

Specialty: therapeutic classes with either, or any combination of, a higher cost per claim and lower claim volume or a route of administration such as infused or physician injectable drugs.

The CMS Office of the Actuary projects that Medicaid as a whole is expected to average 5.8 percent annual growth, and prescription drug spending will increase an average of 6.3 percent per year from 2017 through 2026, the fastest amongst the major sectors of health care spending.

[23] MAGELLAN RX MGMT., *supra* note 14, at 6.

This is primarily attributed to growth in utilization and pricing trends for high-cost specialty drugs.[24] Although the net drug spend constitutes only six percent of Medicaid total spending, the high cost of specialty drugs continues to be a concern among Medicaid policy directors looking to control future spending.[25] State Medicaid programs continue to face the challenges of providing access to new, high-cost specialty drugs while working within the confines of state budgets. Specialty drug expenditures are expected to reach 45 to 50 percent of total pharmacy spend by 2020. This continual growth will drive states to evaluate program design and how to best allocate available resources in order to provide treatment to beneficiaries that require specialty drugs. Innovative approaches are still developing and it is not clear yet where the balance of best practices will land related to access, quality, and cost. Specialty drug benefit and utilization management represents an opportunity for Oregon to establish innovative best practices and set an example for other state Medicaid programs to follow.

OHA Prescription Drug Benefit Design

OHA provides pharmaceutical benefits to nearly one million beneficiaries through two primary delivery systems. The FFS delivery system is comprised of approximately 150,000 beneficiaries (15 percent), while the CCO delivery system provides services to the remaining beneficiaries.

Currently, there are 15 CCOs providing services to Oregonians throughout various regions of the state who receive health care coverage through Medicaid. Some regions have a single CCO, while others may have multiple CCOs providing services.

Under Oregon Administrative Rule 410-141-0070, CCOs must provide payment for prescription drugs as a covered service with the exception of mental health drugs.[26] OHA pays for covered mental health drugs on a FFS basis and these drugs are not included in the capitation rates. For the purposes of this payment policy, “mental health drugs” are defined as those drugs classified by First Databank, a drug file compendia provider, in the Standard Therapeutic Class equal to Class 07 (ataractics, tranquilizers) and Class 11 (psychostimulants, antidepressants). In addition, lamotrigine and divalproate, although commonly used to treat seizure disorders, are also considered mental health drugs. These mental health drugs are often referred to as the 7-11 Drug Carve-Out List.

The FFS delivery system and each of the 15 CCOs currently establish and maintain their own PDL. Currently, while commonality exists between the various PDLs, the process for establishing and maintaining these PDLs is not consistent. In addition, the pharmacy utilization management tools discussed previously on page 12, including PA criteria, are not uniform or determined through a collaborative process. One notable exception to this statement is related to the hepatitis C class of drugs. This particular class has a uniform PDL and consistent PA criteria across all delivery systems. This uniformity and alignment was achieved in response to access concerns

[24] Press Release, CMS Office of the Actuary releases 2017-2026 Projections of National Health Expenditures (Feb. 14, 2018), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-02-14.html.
[25] YOUNG & GARFIELD, *supra* note 10, at 1.
[26] OR. ADMIN. R. 410-141-0070 (2017).

outlined by CMS in MDRP Release Number 172.[27] For this class of drugs, the FFS and CCO delivery systems working in collaboration with DURM and the P&T Committee developed a uniform and consistent PDL policy. The approach included the implementation of a risk corridor in the CCO contracts.

PDL Development and Maintenance Processes

OHA maintains the FFS PDL and PA criteria in consultation with their P&T Committee with clinical support and evidence-based research provided by DURM. The process is primarily based upon evidence based review of safety and efficacy, utilization of experts, and transparency; net cost is a secondary consideration. The OHA FFS process includes a public meeting forum which provides a level of transparency to the resulting PDL.[28] The National Academy for State Health Policy has recognized the OHA PDL process in an April 2016 publication, noting, "While other states operate similar clinical groups reviewing pharmaceutical and therapeutic products, Oregon's program is distinguished by the involvement of experts in the field of evidence-based policy making, introducing a heighted level of independent scrutiny to the process, and that process is transparent to the public."[29] The FFS program, working in concert with their contracted multi-state pooling program, the Sovereign States Drug Consortium (SSDC), may obtain supplemental rebates from drug manufacturers in addition to the statutorily required federal rebates.

The SSDC is a collaborative group of state Medicaid programs, in which members are collectively focused on providing quality pharmaceutical care while controlling costs. The primary activity of the SSDC is to negotiate rebates that are in addition to those required under the federal MDRP. The SSDC also provides a forum for member states to cooperate in other areas of pharmacy benefit administration and management in Medicaid and other publicly-funded pharmacy benefit programs.

Each CCO in Oregon maintains their own PDL and associated PA criteria by working within their delivery system and their contracted PBM. The CCO PDL process is generally not open to the public and the resulting PDL is not subject to comprehensive review and approval by OHA. The CCOs, through their contracted PBM, may establish rebate agreements with drug manufacturers for preferred status on the CCO PDL. These rebates are paid by the manufacturer to the CCO's PBM, in addition to the federal rebates that are statutorily provided directly to the state.

Outpatient Covered Drug Benefit – Claims and Payment Summary

The PDLs maintained by the FFS and CCO delivery systems are only applicable to a subset of the overall covered drug benefit. Based on data from the DURM Drug Utilization Review (DUR) Report for the first quarter of 2018, the annual total spend for the entire outpatient covered drug benefit is comprised of approximately $863 million S&F. This includes expenditures for pharmacy

[27] Medicaid Drug Rebate Program Notice Release No. 172, Ctrs. for Medicare & Medicaid Servs., Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.
[28] *Drug Use Research and Management: Policies and Procedures*, OR. STATE UNIV. COLL. OF PHARMACY, https://pharmacy.oregonstate.edu/drug-policy/oregon-pharmacy-therapeutics-committee/policies-and-procedures (last visited July 17, 2018).
[29] ELLEN SCHNEITER, NAT'L ACAD. FOR STATE HEALTH POLICY, STATES AND PRESCRIPTION DRUGS: AN OVERVIEW OF STATE PROGRAMS TO REIN IN COSTS 5 (2016), https://nashp.org/wp-content/uploads/2016/04/Drug-Brief1.pdf.

claims, as well as physician-administered drugs billed via procedure coded drug medical claims, which are not subject to a PDL. Pharmacy claims comprise approximately 82 percent of overall outpatient drug spend ($706 million S&F). The pharmacy claim population included in this analysis, after data exclusions referenced on page 32, represents approximately 92 percent of the $706 million.

CCOs currently pay for approximately 77 percent of the state's Medicaid outpatient drug claims (by claim count), including both pharmacy claims and physician-administered drugs billed via procedure coded drug medical claims. These claims total approximately $700 million S&F and represent 81 percent of Medicaid outpatient drug expenditures. Pharmacy claims represent 87 percent of all CCO outpatient drug claims, totaling approximately $571 million S&F. The relative percentage of claims and the percentage of spend paid by the CCOs for all outpatient covered drug claims has remained about the same over the past three years based on DURM drug utilization reports. The CCO pharmacy claim population included in this analysis after data exclusions on page 32, represents approximately 93 percent of the $571 million S&F. *Table 3* summarizes the gross spend and claim count by delivery system.

Table 3: Gross Spend and Claim Count by Delivery System[30]

Delivery System	Total Outpatient Drug Spend	Pharmacy Drug Spend	Physician Administered Drug Spend	Average Monthly Claim Count	Average Monthly Pharmacy Claim Count	Average Monthly Physician Administered Drug Claim Count
FFS	$163M (19%)	$135M (83%)	$28M (17%)	233,487 (23%)	214,868 (92%)	18,619 (8%)
CCO	$700M (81%)	$571M (82%)	$129M (18%)	786,085 (77%)	681,305 (87%)	104,780 (13%)
BOTH	$863M (100%)	$706M (82%)	$157M (18%)	1,019,572 (100%)	896,173 (88%)	123,399 (12%)

Myers and Stauffer utilized a data set provided by OHA for the PDL analysis to generate the claims payment and utilization summaries on the following pages for all pharmacy claims. The data included pharmacy claims with a date of service between January 1, 2017 and December 31, 2017.

A significant portion (85 percent) of the total pharmacy drug claims included in the analysis were for generic drugs. While brand drugs only accounted for 15 percent of the claim population, they represented 75 percent of spend. This inverse relationship of claim count versus claim spend occurs across all Medicaid programs. The GDR was calculated by dividing the number of generic drug claims by the total number of drug claims. This was performed utilizing claims for each delivery system and resulted in a GDR of approximately 83 percent, in aggregate, for the CCO delivery systems, and over 90 percent for the FFS delivery system. The higher GDR for FFS is partially due to the high utilization of generic drugs from the 7-11 Drug Carve-Out List. *Chart 1* below illustrates pharmacy spend and claims by brand versus generic designation by delivery system.

[30] OR. STATE UNIV. COLL. OF PHARMACY, PHARMACY UTILIZATION REPORT: OCTOBER 2016—JUNE 2017 (forthcoming) (on file with author).

Chart 1: Brand versus Generic Claims and Spend by Delivery System – 2017 Service Dates

Table 4 below illustrates OHA gross pharmacy claim payment averages and are categorized in various groupings by delivery system.

Table 4: Average Gross Payment per Pharmacy Claim by Delivery System – 2017 Service Dates

	Overall	FFS	CCO
All	$66.62	$52.82	$70.68
Brand	$326.19	$333.18	$325.03
Generic	$19.76	$23.14	$18.68
Specialty	$3,119.39	$2,046.01	$3,295.16
Non-Specialty	$40.99	$42.52	$40.54
Hepatitis C	$21,751.99	$24,601.39	$21,653.28
7-11 Drug Carve-Out	$53.78	$53.75	$145.99*
Non-Carve-Out	$69.22	$50.18	$70.68

**A small number of claims for drugs on the 7-11 Drug Carve-Out List existed in the CCO claims data.*

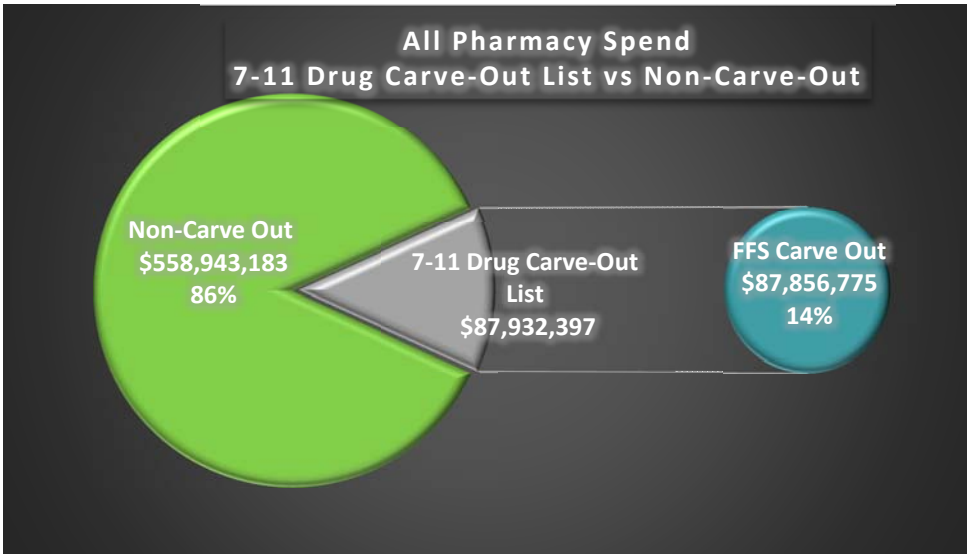
Although specialty drug claims account for less than one percent of all OHA pharmacy claims, total OHA expenditures for specialty drugs represent almost 40 percent of overall pharmacy spend. Currently, CCO specialty spend for non-preferred specialty drugs, based on the FFS PDL designation, is approximately 23 percent. *Chart 2* below illustrates the breakdown.

Chart 2: Specialty Pharmacy Claims and Spend by Delivery System – 2017 Service Dates

Claims were identified as specialty if the NDC existed on the Myers and Stauffer Specialty Drug List. This list is utilized to perform various analyses regarding specialty utilization and spend. The initial list was established by comparing numerous specialty drug lists published by specialty pharmacies and PBMs and was subsequently reviewed by a team of pharmacists. On a weekly basis, compendia drug files are reviewed by a team of pharmacists to identify new drugs that are potential candidates for addition to the list. Several considerations are made to determine if a drug should be added to the specialty list, including but not limited to, cost of therapy, indication, route of administration, drug distribution mechanism, the requirement of special handling, and orphan drug designation.

CCOs are not required to make payment for drugs on the 7-11 Carve-Out Drug List as these are covered through the FFS benefit. The portion of spend for drugs on this list represents 14 percent of the total pharmacy spend. As expected, a review of the claims data indicated that the FFS delivery system paid for 99.9 percent of the 7-11 Carve-Out Drug List spend. *Chart 3* below illustrates the breakdown.

Chart 3: 7-11 Drug Carve-Out List Pharmacy Spend by Delivery System – 2017 Service Dates



Under the current pharmacy benefit design, each CCO establishes and maintains their own PDL; however, a large portion of CCO utilization and spend is already aligned with the FFS PDL. Only nine percent of the CCO claims and 26 percent of the CCO spend were for FFS non-preferred drugs under the FFS PDL. This result is driven by the high utilization of generic drugs in both delivery systems, the existing alignment requirement of the hepatitis C class, the 7-11 Drug Carve-Out List, and a subset of covered outpatient drugs not subject to the FFS PDL. *Chart 4 and Chart 5* on the following page illustrates the breakdown of spend and claims.

Chart 4: CCO Spend Breakdown by FFS PDL Designation – 2017 Service Dates

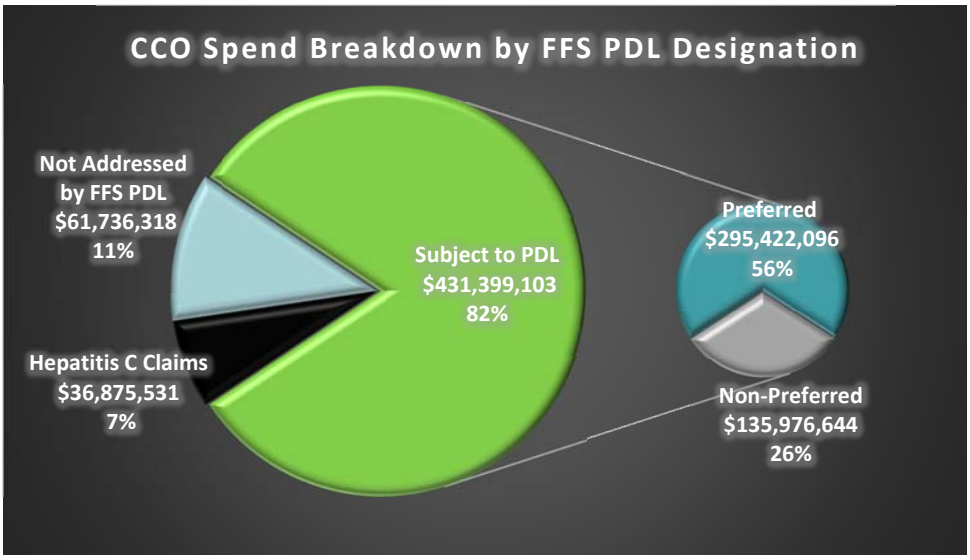
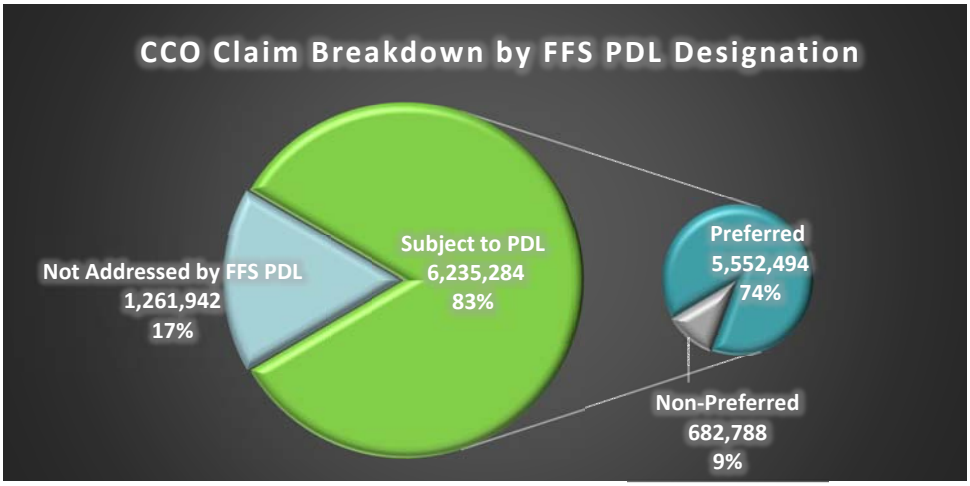
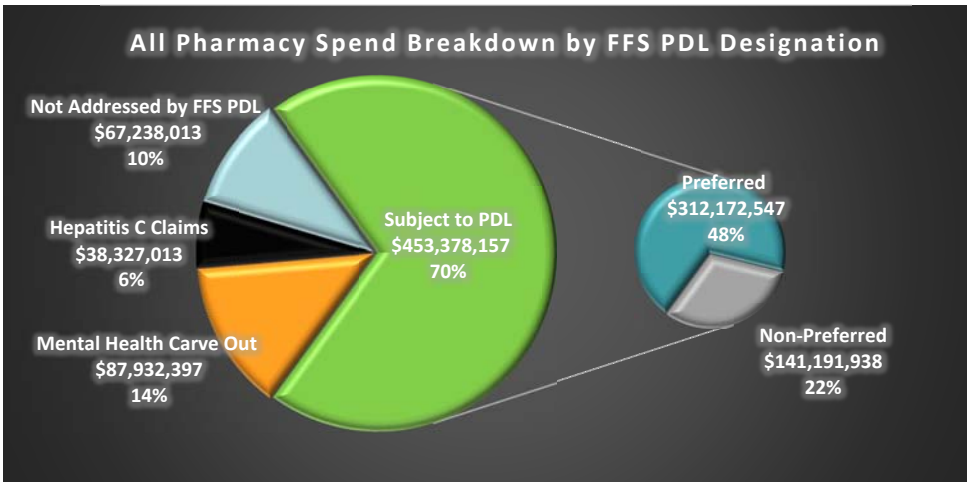


Chart 5: CCO Claim Breakdown by FFS PDL Designation – 2017 Service Dates



*Hepatitis C claims are not included in *Chart 5* as they represent only 0.02% of CCO claims.

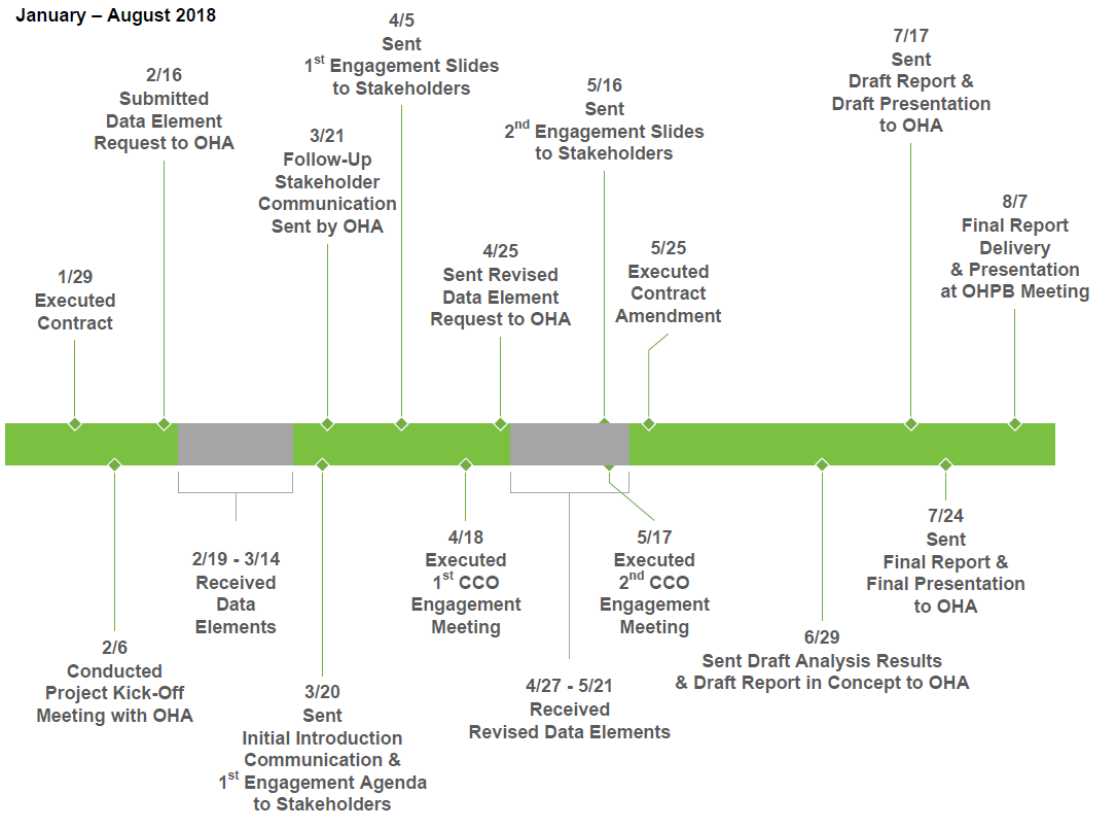
Chart 6: CCO and FFS Spend Breakdown by FFS PDL Designation – 2017 Service Dates



The claims and payment summary charts and tables above illustrate the allocation of total spend and claims by delivery system. In addition, the data demonstrate the high GDR existing in both delivery systems along with the inverse relationship between a high GDR and the amount of spend attributable to generic drug claims. Overall, brand drug spend and the subset of specialty spend (primarily comprised of brand drugs) represent the majority of total drug spend on a program wide basis. These two spend areas represent the greatest areas for savings opportunity when considering a single PDL or an aligned PDL approach. Specialty spending and uniformity of benefit design (including physician administered drugs billed on medical claims) also represent opportunities for program wide collaboration between the FFS delivery system and the CCO delivery systems. Due to the inherent existence of the high generic dispensing rates in both delivery systems it is evident that there is already a high degree of PDL alignment taking place. For the drugs subject to the FFS PDL, 56 percent of the total CCO spend and 74 percent of total CCO claims were for preferred FFS drugs and are essentially already aligned. In addition, the 7-11 Drug Carve-Out List paid for through the FFS delivery system represents 14 percent of total program spend. Lastly, the hepatitis C therapeutic class is already aligned and has consistent prior authorization criteria, representing approximately 6 percent of total program spend. *Chart 6* above illustrates the overall spend, inclusive of both CCO and FFS delivery systems, partitioned by FFS PDL designation.

PDL Evaluation Key Milestones

Throughout the course of the project, Myers and Stauffer conducted bi-weekly update calls with OHA. A dedicated email address was established to allow for continual CCO feedback, questions, and interaction throughout the process. The timeline below highlights key milestones during the course of the project.



Options for Consideration

Myers and Stauffer considered and assessed three approaches related to the administration of the PDLs: 1) a single PDL approach; 2) an aligned PDL approach; and 3) status quo. Key considerations in the evaluation and formulation of recommendations related to these three approaches included operational realities, measurable program savings, and consideration of the impact to the CCOs, OHA, and the provider community. It is important to note that the implementation of a single or aligned PDL approach would not result in carving out the prescription drug benefit from the CCO capitation payments.

Single PDL

A single PDL approach would obligate the CCOs to utilize and adhere to the FFS PDL for all therapeutic classes. This would include consistent application of utilization management tools and PA criteria across all delivery systems.

Implementation and Operational Realities

Implementation of a single PDL approach in an established delivery system environment, such as the current state of the Oregon Medicaid pharmacy benefit, requires careful consideration and attention to many details. Wholesale changes, especially when considering the fact that Oregon has 15 CCOs operating and managing their own PDLs, have a greater potential to result in disruption to patient care and access to medications patients are currently taking. In addition to beneficiary disruption, the program must also consider the impact to prescribers and pharmacies in regard to therapy conversions and PAs. Capitation rate impact must also be considered, especially since the CCOs receive capitation rates with a five-year, 3.4 percent spending growth target for total cost of care. Configuration changes to CCOs' pharmacy claims processing systems and the associated cost must be considered. The breadth and depth of the PDL changes, combined with the extended implementation timeframe needed, will determine the overall impact to all stakeholders, including the bandwidth and feasibility of OHA to implement such a change. In addition, OHA must balance program priorities with the return on investment necessary to support a change of this magnitude in light of other opportunities that could be pursued. While a single PDL could be an ideal approach for a new program or a long-term solution for an existing program, moving directly from the current approach to a single PDL does not allow adequate time for OHA to properly monitor and evaluate the associated operational and financial outcomes.

Aligned PDL

An aligned PDL approach would obligate the CCOs to utilize the FFS PDL for only a select number of therapeutic classes.

Implementation and Operational Realities

Implementation of an aligned PDL has many of the same considerations as mentioned above with the single PDL approach. While the considerations are similar, the overall magnitude of the aligned PDL approach is much smaller than that in the single PDL approach. This approach limits the initial number of therapeutic classes for alignment and prioritizes those classes identified with the greatest program savings for OHA. In addition, this minimizes disruption to all stakeholders,

limits the potential capitation rate impact, and allows time to measure and monitor the impact of the initial recommended therapeutic classes. The aligned PDL approach could be implemented over a shorter duration of time and allow for other OHA priorities such as collaborative efforts related to utilization management of specialty pharmaceuticals.

Status Quo

Continuing with the status quo would allow the CCOs to continue to operate and maintain their PDLs without regard to the FFS PDL. However, the current approach does not take advantage of the administrative and financial opportunities available through a single or aligned PDL.

Stakeholder Considerations

Myers and Stauffer conducted research and reviewed existing literature and publications regarding implementation of a single or aligned PDL approach. Feedback was solicited throughout the project from the 15 CCOs via two webinars and a dedicated email address. The CCOs also provided two whitepapers on the subject of a single or aligned PDL.[31,32] In addition, conversations were held with representatives of other state Medicaid programs that have implemented or are considering implementation of a single or aligned PDL. Based upon these activities, Myers and Stauffer has summarized the relevant common themes, findings, and observations outlined on the following pages.

Perspectives and Positions Surrounding a Single or Aligned PDL

There are several common considerations noted in a number of publications with both supporting and opposing positions regarding PDL approaches. The following table illustrates and describes the common considerations and the varying positions for each.

Table 5: Single or Aligned PDL Considerations

Single or Aligned PDL Considerations	Supporting Position	Opposing Position
Improved Provider Experience and Administrative Simplification	▪ Creates administrative efficiencies and advantages for prescribers and enrolled pharmacies. ▪ Reduces the burden of tracking multiple PDLs which are published in variable formats and locations updated at different frequencies. ▪ Reduces the burden of navigating different PA criteria and utilization management tools. ▪ Provides for more uniformity and simplicity across the 16 unique PDLs. ▪ Reduces Oregon Medicaid provider concerns and complaints related to administrative burden.	▪ Pharmacies and prescribers routinely deal with multiple formularies, PDLs, and varying PA requirements from other payers. ▪ Does not eliminate the use of PA completely. ▪ Other tools exist that can be utilized to ease administrative burden, such as electronic PA and electronic prescribing, combined with real-time pharmacy benefit checking and verification.

[31] PRIMARYHEALTH ET AL., *supra* note 3

[32] PRIMARYHEALTH ET AL., PHARMACY BENEFIT ALIGNMENT: PRINCIPLES/CONCEPTS/OPPORTUNITIES/RISK MITIGATION (forthcoming) (on file with author).

Single or Aligned PDL Considerations	Supporting Position	Opposing Position
	▪ Reduces pharmacy burden of PA volume and inventory management challenges.	
Consistent Access	▪ Offers more consistent access for all Medicaid beneficiaries to the same set of medications regardless of the delivery system being utilized.	▪ Diminishes the ability of CCOs to meet the unique need of the communities they serve.
Rebate Maximization/Lower Net Costs	▪ Will result in shifting utilization to medications with the lowest net unit cost after rebate consideration. ▪ Will result in lower net costs for state and federal taxpayers. ▪ After the review of clinical evidence, federal rebates are often the key determinant of the favorable net cost equation for PDL status.	▪ Financial incentives should be provided to each stakeholder to align to lower net cost medications. ▪ Will, in some cases, result in additional up front expenditures by the CCOs. ▪ May require potential adjustment to capitation rates. ▪ Impacts the drug mix being utilized and negatively impacts the finances of the CCO. ▪ Supplemental rebates should be optimized but should not drive health care strategy/structure.
Preferred Multiple Source Brand Drugs Over Generically Equivalent Drugs	▪ Will result in lower net costs for state and federal taxpayers. ▪ Select opportunities may exist with high savings, but minimal capitation rate/GDR impact.	▪ Will result in lower GDRs. ▪ Will result in higher CCO gross expenditures and capitation rate adjustments. ▪ Requires coordination and timing of PDL changes to appropriately capture savings. ▪ Requires pharmacies to maintain a higher inventory for brand drugs that cost more to purchase than the generic alternative.
Improved Member Experience	▪ Minimizes or eliminates the occurrence of Medicaid beneficiaries switching between delivery systems to pursue access to their drug of choice. ▪ Reduces risk of delays in starting or abandoning medication therapy.[33] ▪ May result in improved adherence to the prescribed regimen resulting in improved health outcomes.[34] ▪ Reduces the need for additional pharmacy visits requiring transportation.	▪ Reduces CCOs flexibility to prioritize "whole person" care coordination within their unique and specific population.
Best Practice Development	▪ Allows for coordination between CCOs and FFS on consistent best	▪ May be difficult to agree on best practices when financial interests are not aligned.

[33] AMERICAN MED. ASS'N, 2017 AMA PRIOR AUTHORIZATION PHYSICIAN SURVEY 1 (2017), https://www.ama-assn.org/sites/default/files/media-browser/public/arc/prior-auth-2017.pdf.
[34] MICHELLE LASTER-BRADLEY ET AL., ACS GOV'T HEALTHCARE SOLS., EVALUATION OF THE INDIANA MEDICAID PREFERRED DRUG LIST (PDL) PROGRAM (2006), http://www.in.gov/legislative/igareports/agencyarchive/reports/FSSA56.pdf.

Single or Aligned PDL Considerations	Supporting Position	Opposing Position
	practice approaches to drug benefit design.	
Benefit Administration Transparency	▪ Allows for ongoing collaborations between CCO and FFS delivery systems. ▪ Aligns FFS and CCO, PDL, and PA criteria review processes, improving visibility and transparency. ▪ P&T Committee meetings open to the public. ▪ Increases participation in P&T committee meetings.	▪ Allows drug manufacturers to participate in P&T committee meetings, which could allow them to influence PDL product placement. This, in turn, could result in the inclusion of higher cost products that do not deliver added clinical value in return for the large cost difference to the CCO.
Federal and Supplemental Rebate Transparency	▪ Improves CCOs' understanding and insight of federal and supplemental rebate impact relative to CCO gross cost versus the state's net cost. ▪ Allows OHA to measure the impact to the CCOs' gross expenditures and predict the need to adjust capitation rates when necessary.	▪ No incentives exist for the CCOs to establish PDLs that result in the lowest net cost to the state after rebates are considered.

PDL Environmental Scan

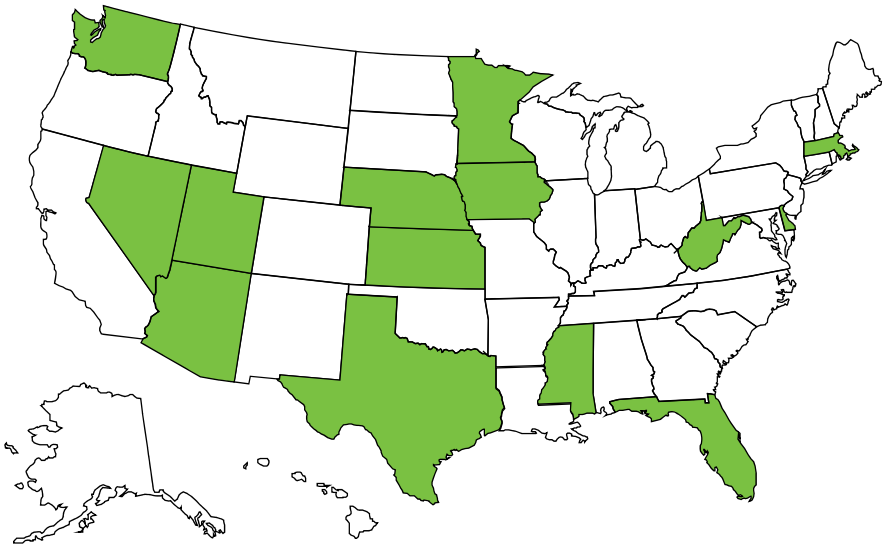
Myers and Stauffer reviewed publicly available information about states that utilize a single or aligned PDL. Based on this review, various approaches were identified across the 51 Medicaid programs with regard to the administrative flexibility of a MCO/CCO to administer and maintain their own PDL. While some states require the MCOs/CCOs to adhere to the FFS PDL, other states do not impose any requirements. A 2014 report by the Menges Group "State Policies Regarding Medicaid MCO Preferred Drug Lists" states "a middle ground policy has been established in several states (e.g., Ohio), where a Medicaid MCO's PDL is required to be largely aligned with the Medicaid fee-for-service PDL." [35]

A number of other states have taken this type of approach, aligning select therapeutic classes as opposed to a single PDL. Some states, such as Alabama and West Virginia, carve out the pharmacy benefit from managed care capitation rates altogether. It is worth noting that an increased number of states are more closely evaluating the change to a single PDL in light of the Medicaid and CHIP Managed Care Final Rule (CMS-2390-F) discussed on page 8. In addition, state Medicaid programs are examining other related areas that can impact PDL spending such as drug pricing transparency, 340B drug discount payment policies.[36,37] MCO/CCO PBM

[35] THE MENGES GROUP, STATE POLICIES REGARDING MEDICAID MCO PREFERRED DRUG LISTS 3 (2014), https://www.themengesgroup.com/upload_file/acap_fact_sheet_on_pdls.pdf.
[36] Informational Letter No. 1638-MC, Iowa Dep't of Human Servs. & Iowa Medicaid Enter., Update 340B Drug Pricing Program (Mar. 21, 2016), https://dhs.iowa.gov/sites/default/files/1638-MC_Update-340B_DrugPricing%20Program.pdf
[37] Ariz. Health Care Cost Containment Sys., 340B FQHC Look-Alike Pharmacy Bill and Reimbursement Requirements Frequently Asked Questions, https://www.azahcccs.gov/Shared/Downloads/Reporting/PerformanceMeasures/Pharmacy/Pharmacy_340BFAQsFinal3_12_2012.pdf (last visited July 26, 2018).

contractual agreements regarding spread pricing[38,39] and drug rebates. The map below, from a recent Louisiana Medicaid stakeholder presentation regarding consideration of a single PDL, indicates that 14 states with managed care currently require the use of a single PDL. It should be noted that other states may utilize a single PDL, but do not have managed care programs and other states with managed care align certain PDL classes or carve out certain drugs or classes from managed care capitation rates.

Chart 7: States with Managed Care Utilizing a Single PDL[40]



State-Specific Efforts

Washington

The most recent state to move forward with the implementation of a single PDL is the State of Washington. The Washington State Health Care Authority (HCA) was required to implement a single Medicaid PDL due to a legislative provision. All MCOs must use the FFS PDL and must not negotiate or collect rebates for drugs listed on the PDL regardless of their preferred or non-preferred designation. HCA noted that the priorities of implementing a single Medicaid PDL involved patient care and access to necessary medications, minimizing patient and provider

[38] Catherine Candisky, *DeWine Threatening to Sue Pharmacy Benefit Managers*, AKRON BEACON J./OHIO.COM (July 23, 2018 8:10PM), https://ohio.com/akron/business/dewine-threatening-to-sue-pharmacy-benefit-managers

[39] HEALTHPLAN DATA SOLS., LLC, EXECUTIVE SUMMARY OF REPORT ON MCP PHARMACY BENEFIT MANAGER PERFORMANCE (2018), http://www.healthtransformation.ohio.gov/Portals/0/Press%20Releases/PBM%20HDS%20Final%20Report%20Executive%20Summary.pdf?ver=2018-06-21-114617-170.

[40] JEREMY PALMER & STEVE LILES, MILLIMAN, LOUISIANA MEDICAID SINGLE PREFERRED DRUG LIST 7 (2018), http://ldh.la.gov/assets/docs/BayouHealth/Pharmacy/Louisiana_Single_PDL-Stakeholders_Presentation-20180427.pdf.

disruption, and providing easy access to the right information for patients, prescribers, and pharmacies.[41]

Texas

The Texas Vendor Drug Program, which administers the Medicaid pharmacy benefit, utilizes a single PDL. Based on concerns from the MCOs operating in Texas, the Vendor Drug Program requested that an actuarial consulting firm perform an analysis to evaluate the estimated financial impact of a mandated single PDL versus an approach with no mandate (i.e.,MCO maintains their own PDL). The results of this analysis estimated that despite the additional rebates collected in the mandated single PDL, the no mandate scenario would be 1.8 percent less costly ($40 million in general revenue) over a two-year period.[42] A second report regarding the financial impact of the Texas mandated single PDL, sponsored by the Texas Association of Health Plans, was published by the Menges Group. The Menges report found that "the current uniform PDL policy is costing Texas taxpayers over $1 million for every four days it remains in effect".[43] Unlike the analysis performed by the actuarial firm, the Menges report could not incorporate the impact of detailed federal and supplemental rebate amounts and relied on publically available aggregated data to estimate net cost per prescription in the aggregate. This difference in approach may have contributed to the large financial discrepancy between the two reports.

Florida

The Florida Medicaid program implemented a single PDL in 2014. A study regarding the effect of Florida's implementation of a single PDL was published in February 2018 in the *Journal of Managed Care & Specialty Pharmacy*.[44] The report concluded that the state-mandated PDL resulted in declines in overall and generic drug use and an increase in drug plan costs. However, a major limitation to this study is that it did not take into account federal or supplemental rebates that the state receives from pharmaceutical manufacturers. Due to this significant limitation, the financial results of this study are not reliable from a net cost impact perspective. A recommendation worth noting from the study is that states need to anticipate increased drug costs for health plans and make equitable adjustments to plan capitation rates. Funding for this study was provided by Express Scripts, a PBM, who provides services to MCOs/CCOs in multiple states.

Louisiana

The Louisiana Medicaid program has been evaluating the implementation of a single PDL and recently held a stakeholder engagement meeting in April 2018 highlighting the rationale behind this evaluation. The presentation indicated that the intent was not to reduce the cost of the Louisiana Medicaid pharmacy program, but rather to address the practical challenges of multiple PDLs faced by their Medicaid members and enrolled providers. However, they did note that they

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[41] DONNA L. SULLIVAN, WASH. STATE HEALTH CARE AUTH., SINGLE MEDICAID PREFERRED DRUG LIST 6 (2017), https://www.dev.hca.wa.gov/assets/program/dur-single-pdl-2017-7-7.pdf.
[42] KHIEM D. NGO, RUDD AND WISDOM, INC., STATE OF TEXAS VENDOR DRUG PROGRAM: FORMULARY CONTROL STATE VS. MCO 1 (2017), https://hhs.texas.gov/sites/default/files/formulary-control-state-vs-mco.pdf.
[43] JOEL MENGES ET AL., THE MENGES GROUP, ASSESSMENT OF MEDICAID MCO PREFERRED DRUG LIST MANAGEMENT IMPACTS 1 (2016), https://www.themengesgroup.com/upload_file/report_on_texas_pdl_february_2016.pdf.
[44] Kiraat D. Munshi et al., *The Effect of Florida Medicaid's State-Mandated Formulary Provision on Prescription Drug Use and Health Plan Costs in a Medicaid Managed Care Plan*, 24 J. OF MANAGED CARE & SPECIALTY PHARMACY 124 (2018), https://www.jmcp.org/doi/pdf/10.18553/jmcp.2018.24.2.124.

were committed to ensuring the change would be budget neutral and any realized savings would be reinvested in the Medicaid pharmacy program.[45]

Preferred Multiple Source Brand Drugs

A consistent concern and operational reality of a single PDL involves the state maintaining preferred status for brand drugs over their available generic equivalents. This occurs when a significant net cost savings is realized by the state because of high federal rebates (and potential supplemental rebates) for brand drugs with recent patent expirations. The primary concern voiced by CCOs is that the generic equivalent is less costly on a gross spend basis, and the CCOs have no financial incentive to maximize rebates collected by the state or lower the net cost (after rebates) to the state.

Selective opportunities for preferring brand drugs over their available generic equivalents do exist and result in lower net cost for state and federal taxpayers.[46] This lower net cost advantage may exist for only a short period of time depending on the level of generic competition or it may go on for an extended period of time in certain situations. For some brand drugs, especially during the six-month exclusivity period following the brand patent expiration, the URAs can result in the net cost for the brand drug to be substantially lower than that of the generic alternative. During the six-month exclusivity period, "the average retail price of the true generic is about 86 percent of the brand drug's retail price without a competing authorized generic, and 82 percent of the brand drug's retail price with a competing authorized generic (FTC 2011). Once the 180-day period expires and other generics enter the market, the generic price drops substantially (Kirchhoff et al. 2018)."[47] In addition, the CPI penalty and best price features of the Medicaid rebate formula may result in substantially lower net costs as opposed to other brand alternatives in the same therapeutic class. While these lower net costs would be realized at the state and federal level, it is important to note that this may result in additional gross expenditures by the CCOs. This has the potential to impact capitation rates and CCO finances, and should be thoroughly evaluated by the State's actuary to understand how the generic drug entry was factored into existing capitation rates.

In order for OHA to capitalize on these opportunities within a more aligned environment, they must have the flexibility to make more efficient and timely changes to the PDL than what currently is in place. This includes identifying when a savings opportunity exists to keep the brand drug as preferred and identifying at what time the savings associated with preferring the brand over the generic is eliminated. It is also important to have sufficient stakeholder coordination and communication in place so enrolled pharmacy providers can properly manage inventory levels and CCOs can configure their claims processing systems. *Chart 8* on the following page illustrates an example of the net savings opportunities that can exist by preferring multiple source brands over their generic equivalent(s) and *Chart 9* provides an illustration of the net cost savings that can exist in a therapeutic class between a multiple-source brand, an equivalent generic, and another brand drug alternative in the same therapeutic class.

[45] PALMER & LILES, *supra* note 40, at 6.
[46] MAGELLAN RX MGMT., *supra* note 14, at 4-5.
[47] MEDICAID AND CHIP PAYMENT AND ACCESS COMM'N, REPORT TO CONGRESS ON MEDICAID AND CHIP 8 (June 2018), https://www.macpac.gov/wp-content/uploads/2018/06/June-2018-Report-to-Congress-on-Medicaid-and-CHIP.pdf.

Chart 8: Brand and Generic Equivalent Price Trending Example

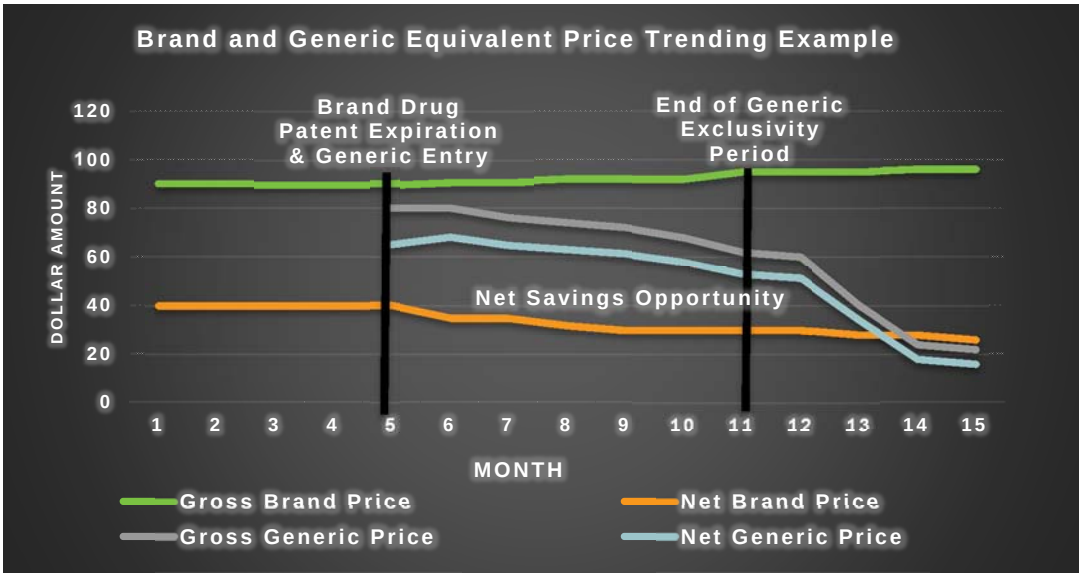
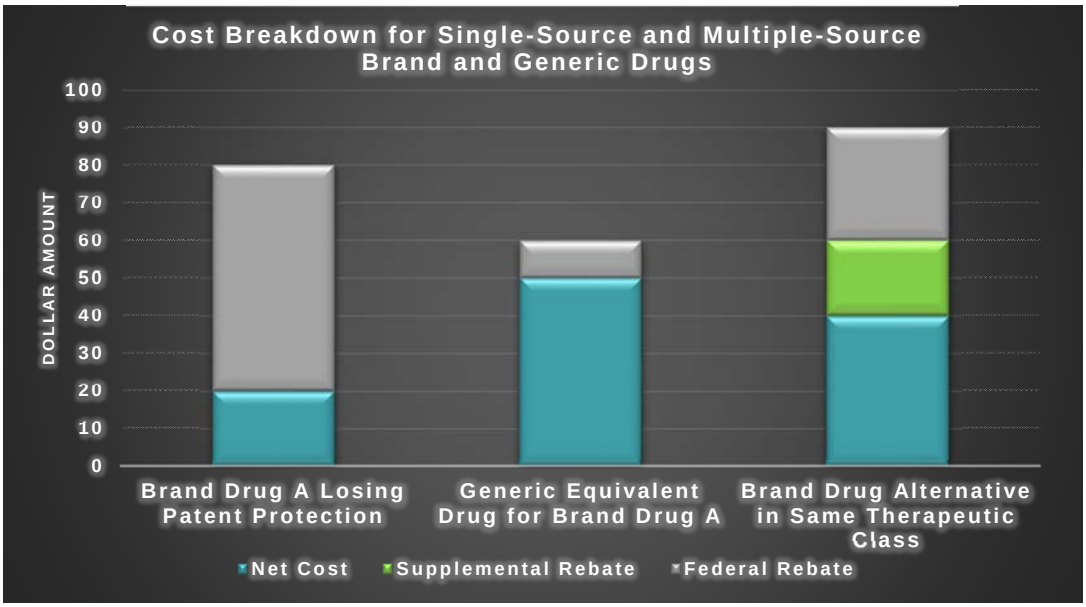


Chart 9: Cost Breakdown for Single-Source and Multiple-Source Brand and Generic Drugs



Data Analysis

Data Acquisition and Validation

For purposes of the PDL analysis, Myers and Stauffer obtained several data sets from OHA and their Medicaid Management Information System (MMIS) vendor. Pharmacy claims and other data elements were requested for dates of service between January 1, 2017 and December 31, 2017. The following data sets were provided:

- *All final paid FFS pharmacy claims grouped by therapeutic class code, NDC, and quarter (OHA).*
- *All final paid CCO pharmacy claims grouped by therapeutic class code, NDC, and quarter (OHA).*
- *All final paid CCO pharmacy claims grouped by therapeutic class code, NDC, CCO Plan ID, and quarter (OHA).*
- *Federal unit rebate quarterly files by NDC (MMIS vendor).*
- *Supplemental rebate quarterly files by NDC (MMIS vendor).*
- *National Council for Prescription Drug Programs (NCPDP) to CMS unit rebate conversion crosswalk by NDC (MMIS vendor).*
- *PDL categorization for FFS by Generic Code Number (GCN) and NDC (MMIS vendor).*
- *Monthly enrollment reports for FFS and each CCO.*

Certain conditions/exclusions were applied to the claims data sets provided by OHA. The following conditions, along with the rationale for their exclusion, are provided below:

- *340B claims: Not eligible for federal rebates.*
- *Title XXI claims: Not eligible for federal rebates under the MDRP.*
- *Compound drug claims: Inconsistent claims data, minimal expenditures, and limited PDL implications.*
- *Indian Health Services (IHS) claims: Paid via all-inclusive rate.*
- *Third-party liability claims: PDL PA claim editing is bypassed and State is not primary payer.*
- *Medicare Part B crossover claims: PDL PA claim editing is bypassed and State is not primary payer.*

To ensure the quality and accuracy of the pharmacy claims data sets, the following validation checks were performed:

- *Data provided by OHA to Myers and Stauffer was obtained from the same source used for rebate invoicing and capitation rate calculations.*
- *Data provided to Myers and Stauffer was reviewed and validated by OHA actuarial staff.*

- *Myers and Stauffer calculated key pharmacy utilization metrics such as GDRs, average payment rates per claim, drug claim expenditures, and claim counts and compared these metrics to OHA published DUR reports for reasonability.*

Analysis Calculation Methodology

The methodology utilized by Myers and Stauffer for purposes of estimating the fiscal impact can be summarized into three steps: 1) baseline calculations and aggregation; 2) post-alignment modeling and calculations; and 3) post-alignment impact calculation. For purposes of illustration, the specific steps and example calculation tables are included below.

Step One: Baseline Calculations and Aggregation.

- *Sum CCO 2017 spend, claims, and units by NDC.*
- *Calculate average CCO spend per claim by NDC (CCO spend ÷ CCO claims).*
- *Calculate rebates (federal and supplemental), applying conversions when applicable, for CCO claims by NDC (CCO units x URA).*
- *Calculate average rebate amount per CCO claim by NDC (rebates ÷ CCO claims).*
- *Calculate average net cost per claim by NDC (average CCO spend per claim - average rebate per claim).*
- *Reprice CCO 2017 claims by NDC and compare to actual CCO spend for reasonability (WAC per unit (effective December 31, 2017) x CCO units).*
- *Compare average CCO units per claim and average CCO days supply per claim across all NDCs within the therapeutic class to ensure consistency and reasonability for claim interchange.*
- *Evaluate drugs within each therapeutic class and evaluate clinical reasonability for claim interchange (i.e., insulin therapeutic class: long-acting, intermediate-acting, short-acting, etc.).*
- *Assign FFS PDL designation to the NDCs of the CCO claims and sum total of CCO claims categorized as non-preferred and preferred.*
- *Calculate existing preferred and non-preferred market share within the therapeutic class.*

Pre-Alignment: CCO Spend and Utilization – 2017 Service Dates

FFS PDL Designation	Drug	NDC	Market Share	Spend	Claims	Units	Average Spend per Claim	Federal Unit Rebate Amount	Supp. Unit Rebate Amount	Rebates	Average Rebate per Claim	Net Spend	Net Spend per Claim
Preferred	Drug A	NDC 1	7%	$350,000	700	21,000	$500	$16.66667	$ -	$350,000	$500	$0	$0
Non-Preferred	Drug B	NDC 2	93%	$3,952,500	9,300	279,000	$425	$3.33333	$ -	$930,000	$100	$3,022,500	$325
Total				**$4,302,500**	**10,000**					**$1,280,000**		**$3,022,500**	

Step Two: Post-Alignment Modeling and Calculations.

- *Calculate the post-alignment CCO claim breakdown by NDC by shifting variable percentages of CCO claims designated non-preferred to preferred drug claims (100 percent, 90 percent, and 75 percent).*
  - *If more than one FFS preferred NDC exists, shift post-alignment claims based on CCO market share breakdown between the preferred NDCs.*
- *Calculate CCO estimated post-alignment spend by NDC (CCO post-alignment claims x pre-alignment average spend per claim).*
- *Calculate the estimated post-alignment rebates by NDC (CCO post-alignment claims x pre-alignment average rebate per claim).*
- *Calculate the estimated post-alignment net spend (CCO post-alignment spend - post-alignment rebates).*

FFS PDL Designation	Drug	NDC	Claims	Average Spend per Claim	Average Rebate per Claim	Spend	Rebates	Net Spend
Post-Alignment: Assumes 100% Conversion of Non-Preferred to Preferred								
Preferred	Drug A	NDC 1	10,000	$500	$500	$5,000,000	$5,000,000	$0
Non-Preferred	Drug B	NDC 2	0	$425	$100	$0	$0	$0
Total			**10,000**			**$5,000,000**	**$5,000,000**	**$0**
Post-Alignment: Assumes 90% Conversion of Non-Preferred to Preferred								
FFS PDL Designation	**Drug**	**NDC**	**Claims**	**Average Spend per Claim**	**Average Rebate per Claim**	**Spend**	**Rebates**	**Net Spend**
Preferred	Drug A	NDC 1	9,070	$500	$500	$4,535,000	$4,535,000	$0
Non-Preferred	Drug B	NDC 2	930	$425	$100	$395,250	$93,000	$302,250
Total			**10,000**			**$4,930,250**	**$4,628,000**	**$302,250**
Post-Alignment: Assumes 75% Conversion of Non-Preferred to Preferred								
FFS PDL Designation	**Drug**	**NDC**	**Claims**	**Average Spend per Claim**	**Average Rebate per Claim**	**Spend**	**Rebates**	**Net Spend**
Preferred	Drug A	NDC 1	7,675	$500	$500	$3,837,500	$3,837,500	$0
Non-Preferred	Drug B	NDC 2	2,325	$425	$100	$988,125	$232,500	$755,625
Total			**10,000**			**$4,825,625**	**$4,070,000**	**$755,625**

Step Three: Post-Alignment Impact Calculation.

- *Calculate the estimated post-alignment impact range based on non-preferred claim conversion percentages (100 percent, 90 percent, and 75 percent).*
  - *CCO spend impact = post-alignment spend - pre-alignment spend.*
  - *Rebate collection impact = post-alignment rebate - pre-alignment rebate.*
  - *Net impact (fiscal savings) = rebate collection impact - CCO spend impact OR pre-alignment net spend - post-alignment net spend.*

100% Non-Preferred Conversion	**Spend**	**Rebates**	**Net Spend**
Pre-Alignment	$4,302,500	$1,280,000	$3,022,500
Post-Alignment	$5,000,000	$5,000,000	$0
Net Impact	$697,500	$3,720,000	$3,022,500
90% Non-Preferred Conversion	**Spend**	**Rebates**	**Net Spend**
Pre-Alignment	$4,302,500	$1,280,000	$3,022,500
Post-Alignment	$4,930,250	$4,628,000	$302,250
Net Impact	$627,750	$3,348,000	$2,720,250
75% Non-Preferred Conversion	**Spend**	**Rebates**	**Net Spend**
Pre-Alignment	$4,302,500	$1,280,000	$3,022,500
Post-Alignment	$4,825,625	$4,070,000	$755,625
Net Impact	$523,125	$2,790,000	$2,266,875
Estimated range of additional CCO spend = $523K – $698K Estimated range of additional rebates collected = $2.8M – $3.7M (S&F) Estmated range of potential net savings = $2.3M – $3.0M (S&F)			

Data Results

Based upon the results of the post-alignment calculations, therapeutic classes with the greatest potential for net savings were identified and further evaluated to ensure they were appropriate for alignment recommendation. Due to the proprietary and confidential nature of both federal and supplemental rebates, estimated annual net savings are not quantified by the specific therapeutic class in this public report; however, these specific estimates will be provided to OHA for internal use and verification. *Table 6* below includes those therapeutic classes selected for initial alignment and the estimated range of potential annual net savings.

Table 6: Estimated Range of Annual Net Savings for Selected Therapeutic Classes – Ordered by Savings Opportunity Descending

Therapeutic Class	Estimated Annual Net Savings Range (S&F)	Estimated Annual Net Savings State Only Dollars**
Insulins*	$17 million - $22 million 74%	$4.75 million - $6.25 million
Multiple Sclerosis Agents		
Biologics for Auto-Immune Conditions		
Pulmonary Anti-Hypertensives	$6 million - $8 million 26%	$1.75 million - $2.25 million
Short-Acting Beta-Agonists Inhalers		
Diabetes, GLP-1 Receptor Agonists		
Inhaled Corticosteroids		
Long-Acting Inhaled Anticholinergics		
Pancreatic Enzymes		
Cystic Fibrosis, Inhaled Aminoglycosides		
Growth Hormones		
Total	**$23 million – $30 million 100%**	**$6.5 million – $8.5 million**

***The estimated fiscal impact for the insulin therapeutic class does not include potential savings related to the interchange of Admelog® and Humalog®. Admelog was not commercially available until 2018, therefore was not included in the claims or rebate data analyzed by Myers and Stauffer. Inclusion of this interchange would increase the estimated savings.

****In order to estimate the financial impact in state only dollars Myers and Stauffer applied a blended FMAP of 72%. The blended FMAP was provided by OHA and is an estimate based upon the enrolled Oregon Medicaid population.

Based on the suggested classes for alignment, the State's actuary should perform an analysis to determine the potential impact to the CCO capitation rate calculation and OHA should confirm with more current data that claims utilization mix or other factors that could impact the estimated net savings are comparable to that contained in the data set provided.

Assumptions, Exclusions, and Limitations of Analysis

The following assumptions, exclusions, and limitations of analysis are noted relative to issues encountered or considerations made in compilation of this fiscal analysis.

- *The analysis was based on outpatient pharmacy claims data with dates of service from January 1, 2017 through December 31, 2017. Claims data was obtained from OHA on April 27, 2018 and is based on data at that point in time. Additional paid claims data within these dates of service may alter the results of this analysis.*
- *Myers and Stauffer did not adjust its analysis to remove the impact of any pharmacy initiatives or pharmacy program changes that may have occurred or had an impact during or after the study period reviewed.*
- *For this analysis, Myers and Stauffer relied upon data, as well as other sources of information as described in this report. Myers and Stauffer relied upon this data without independent audit; however, the data was reviewed for reasonableness and consistency.*
- *This review may not identify all data imperfections. We assume the data provided is both accurate and complete based upon the validation performed by OHA. The results of our analysis are dependent upon this assumption.*
- *Due to the dynamic nature of the prescription drug marketplace, it is difficult to predict precise financial impacts; therefore, estimates are presented as a range based upon various levels of market share shifts for the selected therapeutic classes. We assumed that the aggregate utilization of drugs within a therapeutic class will not materially differ when comparing the current approach to an aligned approach.*
- *The estimated ranges were calculated based upon 2017 data and cannot predict or account for subsequent changes to the 16 PDLs, utilization mix, drug pricing, federal and/or supplemental rebate amounts, including offsets, beneficiary enrollment, or regulatory changes that may impact prescription drug payment or Medicaid funding.*
- *Myers and Stauffer did not have visibility or access to manufacturer-provided rebates or other remuneration obtained by CCOs or their contracted PBMs; therefore, these amounts are not accounted for within the analysis. These rebates or other remuneration should be considered by the State's actuarial unit when capitation rates are calculated.*
- *Due to the proprietary and confidential nature of federal and supplemental drug rebates, the estimates were provided in the aggregate to avoid any potential disclosure of this sensitive financial information.*
- *This PDL analysis report, and the recommendations contained within, are only applicable to the Oregon Medicaid program. Each Medicaid program should carefully evaluate their own program in the context of its specific structure, pharmacy program design, rebate programs, and federal matching considerations.*

Single or Aligned PDL Recommendation

Summary Observations, Recommendations, and Best Practices

Based upon the activities conducted, Myers and Stauffer recommends OHPB and OHA consider and evaluate the following:

- *1) Consider pursuing an aligned PDL strategy and consistent pharmacy utilization management tools, including PA criteria for the recommended 11 therapeutic classes or subset listed on page 36. The classes identified will not impact overall GDRs or negatively impact the relative drug mix. The estimated range of annual fiscal savings associated with these classes is $23 to $30 million S&F with an estimated range of state share of $6.5 to $8.5 million.*
- *2) Develop a regulatory strategy and work plan for necessary legislative, rule making, procedural, or SPA activities related to an aligned PDL.*
- *3) Measure and regularly monitor fiscal performance for current and future selected therapeutic classes chosen for alignment.*
- *4) OHA, with input provided by the DURM, the Oregon P&T, and the CCOs, should become the sole decision maker with regard to current and future therapeutic classes for PDL alignment. These therapeutic classes and related drugs will provide clear and meaningful net cost advantages for the state and federal taxpayers as the current approach has a certain degree of misaligned/competing financial interests.*
- *5) The CCOs should collaborate and actively provide collective input in the public P&T meeting process as a means to establish consistent utilization management tools and best practices between the FFS and CCO delivery systems.*
- *6) Examine, and as necessary, adjust CCO capitation rates to reflect additional expenditures they may experience due to the change to an aligned PDL. Particular attention should be directed at the transparency of the pharmacy encounter claims submitted by the CCOs, and ensure the understanding of the relationship of the encounter pharmacy payment amounts as related to the amounts actually paid to the pharmacies by their contracted PBMs. In addition, any rebates or other remuneration obtained by the CCO or their contracted PBMs from drug manufacturers should be quantified for purposes of CCO contracting transparency and capitation rate setting.*
- *7) Alternatively, consider the use of an Administrative Services Organization model for aligned classes where OHA pays administrative fees to the CCOs for claims processing-related activities and reimburses the CCO directly for aligned therapeutic class pharmacy expenditures.*
- *8) Current mechanisms to review and utilize the various PDL formats are difficult and cumbersome. OHA, DURM, and the CCOs should collectively develop a user friendly consolidated PDL format with electronic search capabilities for the benefit of prescribers, pharmacies, program beneficiaries, and other interested parties. The resulting PDL format should also include utilization criteria and required PA forms associated with the*

specific drugs and/or therapeutic classes. Aligned therapeutic classes should be clearly noted.

- *9) Given the current and predicted expenditure growth of specialty pharmaceuticals, OHA, DURM, and the CCOs should collaboratively focus their collective expertise on implementing aligned utilization management strategies for specialty drugs. These specialty drugs include drugs dispensed by pharmacies and billed through pharmacy claims, as well as those purchased/administered by enrolled providers and billed through medical claims. The respective stakeholders should examine the role and feasibility of VBP arrangements as a potential strategy to manage specialty pharmaceutical spend.*
- *10) OHA should evaluate the "provider prevails" requirement established under ORS 414.334 to determine the current associated fiscal impact and determine if regulatory action should be pursued to revisit this requirement. OHA should consider optimizing the use of existing utilization management tools, such as step therapy, to maximize the use of preferred drugs providing the most value and ensure medical necessity of non-preferred drugs.*
- *11) Given the substantial national growth of 340B contract pharmacies and utilization of 340B drugs in recent years, OHA should carefully examine the drug utilization, expenditures, reimbursement amounts, and contractual requirements for 340B drugs in the CCO delivery systems. Currently, an OHA payment policy does not exist regarding CCO payment for covered outpatient drugs dispensed or administered by 340B covered entities and their contract pharmacies. This allows the CCOs to establish their own reimbursement policies for 340B dispensed drugs which may result in the CCO delivery systems paying at or near normal market reimbursement rates for these deeply discounted 340B drugs. OHA is not permitted to collect federal rebates when a 340B program drug has been dispensed; therefore, OHA may not only be grossly overpaying for these 340B drugs, but also sacrificing their ability to collect substantial federal rebates. This is an area that many states are actively evaluating and addressing through state policies or other regulatory channels. It has also gained attention at the federal level, as well as by the National Association of Medicaid Directors, and reports have been issued by both the Office of Inspector General and Government Accountability Office.*

It is important to note that these recommendations to OHPB and OHA represent the viewpoints of Myers and Stauffer and are specific to the State of Oregon Medicaid program. Many other aspects, such as regulatory changes, SPAs, and capitation rate analyses will require additional evaluation and research based upon the direction that is ultimately chosen.

Glossary of Key Terms

340B Drug Discount Program: Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992) requires pharmaceutical manufacturers participating in the Medicaid program to enter into a second agreement with the Secretary under which the manufacturer agrees to provide deep discounts on covered outpatient drugs based directly upon the Medicaid rebate formula. These 340B drugs are purchased by specified government-supported facilities called covered entities. 340B entities include disproportionate share hospitals, as well as specified grantees of the Public Health Service, including certain federally qualified health centers (FQHCs), state-operated AIDS drug assistance programs, the Ryan White CARE Act Title I, Title II, and Title III programs, tuberculosis, black lung, family planning and sexually transmitted disease clinics, hemophilia treatment centers, public housing primary care clinics, homeless clinics, urban Indian clinics, and Native Hawaiian health centers.

Authorized Generic Drug: An authorized generic drug is most commonly used to describe a drug that is approved under a new drug application (NDA) that is marketed without the brand name on its label. It is the exact same drug product as the branded product. An authorized generic may be marketed by the brand name drug company, or another company with the brand company's permission. Typically, the manufacturer sells the authorized generic at a lower cost than the original brand name drug.

Average Manufacturer Price (AMP): The average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. The calculation of AMP excludes the prices paid by certain payers (e.g., Department of Veterans' Affairs, Department of Defense, or Federal Supply Schedule) and non-retail community pharmacy providers (e.g., hospitals, LTC facilities, mail order pharmacies, or MCOs) and certain discounts to wholesalers (e.g., prompt pay or bona fide service fees). The calculation of AMP does not include drug rebates.

Best Price: The lowest price available to any wholesaler, retailer, provider, or paying entity excluding certain governmental payers such as the IHS, Department of Veterans' Affairs, Department of Defense, Public Health Service (including 340B), Federal Supply Schedule, and Medicare Part D plans. Medicaid supplemental rebates are also excluded from the best price calculation.

Brand Drug: A drug that is produced or distributed under an original NDA or biologic licensing application (BLA) approved by the Food and Drug Administration (FDA), covered by a patent, and marketed and sold under a proprietary, trademark-protected name. A brand drug may be a single source drug or an innovator multiple source drug. In addition, some drugs approved under an abbreviated new drug application (ANDA) may be considered a brand name drug by payers based upon price and/or their proprietary name.

Compound Drug Claim: A prescription drug claim involving two or more ingredients that are separately billed within the same claim.

Covered Outpatient Drug: An FDA-approved prescription drug, an OTC drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA-approved insulin which has a manufacturer or labeler who has a Medicaid drug rebate agreement in place with the Secretary of Health and Human Services.

Dispensing Fee: A professional dispensing fee is defined in federal regulations (42 CFR 447.502) as the professional fee that pays for pharmacy costs in excess of the ingredient cost of an outpatient prescription drug each time a drug is dispensed. The dispensing fee covers the pharmacy's costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary.

Drug Mix: An evaluation of the type of drugs prescribed by a licensed health care professional or utilized by a defined population of beneficiaries.

Federal Matching Assistance Percentage: The Medicaid program is jointly funded by the federal government and states. The federal government pays states for a specified percentage of program expenditures, called the Federal Matching Assistance Percentage (FMAP). States must ensure they can fund their share of Medicaid expenditures for the care and services available under their state plan. The FMAP may vary between various program types and specific services provided.

Federal Medicaid Rebates: Federal rebates are based on a statutory formula and are only available to state Medicaid agencies. In general, federal rebates are much higher for brand than generic drugs. Federal rebates account for well over 90 percent of the total rebates collected by state Medicaid agencies. Federal rebates differ in both concept and magnitude from prescription drug rebates in the commercial sector which are more similar to supplemental rebates. Federal rebates are not available under the Title XXI CHIP program.

Generic Dispensing Rate: A standard pharmacy benefit management metric which measures the number of generic claims divided by the total number of drug claims. The generic dispensing rate (GDR) is expressed as a percentage. Higher GDRs are considered important because, for the vast majority of drugs, their usage results in lower overall prescription drug costs.

Generic Drug: A drug that is produced or distributed under an ANDA approved by the FDA. Generic drugs are typically distributed by multiple manufacturers and are rated therapeutically equivalent to a brand drug by the FDA. Drug products evaluated as therapeutically equivalent can be expected to have equal effect and no clinical difference when substituted for the brand product.

Gross Pharmacy Cost: Gross pharmacy cost is equal to the total amount paid to the pharmacy by the PBM. It includes ingredient cost and dispensing fee minus any applicable copay or co-insurance.

Innovator Multiple Source Drug: A multiple source drug that was originally marketed under an original NDA approved by the FDA as a brand drug. A brand drug (i.e., single source drug)

becomes an innovator multiple source drug as it loses its patent protection and generic equivalents become available.

Line Extension Drug: A single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the FDA as a modification to the initial listed drug. The modification represents a new version of the previously approved listed drug, such as a new ester, a new salt or other non-covalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug.

Multiple Source Drug: A drug that is distributed by multiple manufacturers who provide therapeutically equivalent products having the same active ingredient, strength, dosage form and route of administration. For purposes of the MDRP, a multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product that is rated therapeutically equivalent and may include the innovator multiple source drug.

National Drug Code (NDC): An 11-digit code used as a universal product identifier for uniquely identifying and billing prescription drugs.

Net Pharmacy Cost: Net pharmacy cost is equal to gross pharmacy cost paid less federal and supplemental rebates collected by the state Medicaid program.

Non-innovator Multiple Source Drug: A multiple source drug that is not originally marketed under an original NDA. Non-innovator multiple source drugs are commonly referred to as generic drugs and are typically approved under an ANDA.

Non-preferred Drug: Drugs that are not preferred drugs within each therapeutically equivalent or therapeutically similar class of drugs utilizing a PDL. Non-preferred drugs typically require PA or the use of a preferred drug prior to their use.

Over-the-counter (OTC) Drug: A drug that may be obtained without a prescription. In most cases, Medicaid programs still require that a prescription be written for the drug to be reimbursed by Medicaid. In general, most Medicaid programs cover a limited number of OTC drugs.

Pharmacy Benefit Manager (PBM): An organization that manages pharmaceutical benefits for MCOs, CCOs, employers, and other health plans. PBM functions typically include plan benefit design, maintenance of retail, mail and specialty networks, claims processing, help desk administration, PA, utilization management, drug utilization review, rebate negotiation, and formulary/PDL management.

Preferred Drug List (PDL): A listing of commonly utilized preferred and non-preferred drugs. In general, preferred drugs are selected after a clinical and economic review and do not require PA. Non-preferred drugs typically require PA. Typically combined with a supplemental rebate program.

Prior Authorization (PA): PA is required for non-preferred drugs and drugs subject to clinical PA edits. The goal of PA programs is to ensure the client receives pharmaceutical treatment that is both medically appropriate and cost-effective. If a beneficiary presents the pharmacy with a

prescription for a non-preferred drug, the claim will require additional information in order for the claim to be paid and dispensed. There are various levels of PA requirements or other utilization edits depending on the drug.

Rebate: A monetary amount that is returned to a payer or PBM from a drug manufacturer based upon utilization of a drug by a covered beneficiary.

Single Source Drug: A drug that is produced or distributed under an original NDA or BLA approved by the FDA, including a drug product marketed by any cross-licensed labelers or distributors operating under the NDA. Single source drugs are brand drugs that are still under patent and are available only from the manufacturer(s) listed on the application.

Step Therapy: The required use of one or more drugs prior to being able to utilize another drug. Also referred to as step edits. Can be systematically or manually administered through PA.

Supplemental Rebates: Supplemental rebates are obtained by state Medicaid programs through direct contracts with drug manufacturers and are in addition to federal rebates. Supplemental rebates are tied to contracts with the drug manufacturers based upon bidding for market share placement as preferred drugs on the PDL.

Unit Rebate Amount (URA): The rebate amount calculated by CMS that a drug manufacturer must pay under the MDRP. The rebate amount is calculated on a per unit basis for each drug at the NDC level. The specific methodology used is determined by statute and depends on the drug's classification as a single source, innovator multiple source, non-innovator multiple source, a clotting factor drug, or an exclusively pediatric drug. CMS provides the URA to the state on a quarterly basis to assist the state in invoicing the manufacturer. The manufacturer remains liable for the correct calculation of the rebate amount.

Utilization Management Tools: Pharmacy benefit management tools, such as step therapy and PA, which are utilized to ensure prescribed drugs are economical, effective, clinically appropriate, and medically necessary for program beneficiaries.

Wholesale Acquisition Cost (WAC): A list price created by the manufacturer of the drug which is published in drug file compendia. The price paid by a wholesaler (or direct purchaser) in the United States for drugs purchased from the drug's manufacturer or supplier. WAC prices do not represent actual transaction prices and do not include prompt pay or other discounts, rebates, or reductions in price.

About Myers and Stauffer

Myers and Stauffer is a public accounting firm with six engagement teams providing diverse services to state and federal agencies managing government-sponsored health care programs. Specializing in accounting, consulting, program integrity, and operational support services, we currently have active health care-related engagements with Medicaid agencies in 48 states, and with CMS on projects involving both the Medicaid and Medicare programs. For more than 40 years, we have assisted state Medicaid programs with complex compliance and reimbursement issues for pharmacies, hospitals, LTC facilities, home health agencies, FQHCs, rural health clinics, physicians, and other practitioners. At the federal level, Myers and Stauffer provides extensive audit and consulting services to CMS, the U.S. Department of Justice and state Medicaid Fraud Control Units.

Myers and Stauffer administers the Survey of Retail Prices related to the development and maintenance of the National Average Drug Acquisition Cost on behalf of CMS, and provides consultation on value-based purchasing and drug pricing reform. Additional pharmacy experience includes consulting and providing services and financial analysis related to pharmacy pricing and reimbursement, pharmacy cost of dispensing, pharmacy benefit management, PDL analysis, procedure coded/physician administered drug reimbursement, 340B drug program audits, pharmacy claims analysis, and regulation/policy review.

Other health care experience includes, but is not limited to, providing audit and desk review services; assisting in the development of state reimbursement systems; defending reimbursement rates and audit findings from health care providers' administrative and judicial challenges; performing recovery audit contractor services; monitoring MCOs; delivery system payment reform initiatives; and performing data management and analysis services to assist our clients better manage their health care programs. We have earned a reputation for being creative and innovative in assisting our clients to adapt to an ever-changing health care delivery system.

Disclaimer

This PDL analysis report, and the recommendations contained within, are only applicable to the Oregon Medicaid program. Each Medicaid program should carefully evaluate their own program in the context of its specific structure, pharmacy program design, rebate programs, and federal matching considerations.