

WHITE PAPER: HOW A SINGLE STATE-MANDATED PREFERRED DRUG LIST WILL EXACERBATE THE OREGON MEDICAID PHARMACY FUNDING CRISIS

EXECUTIVE SUMMARY

Situation

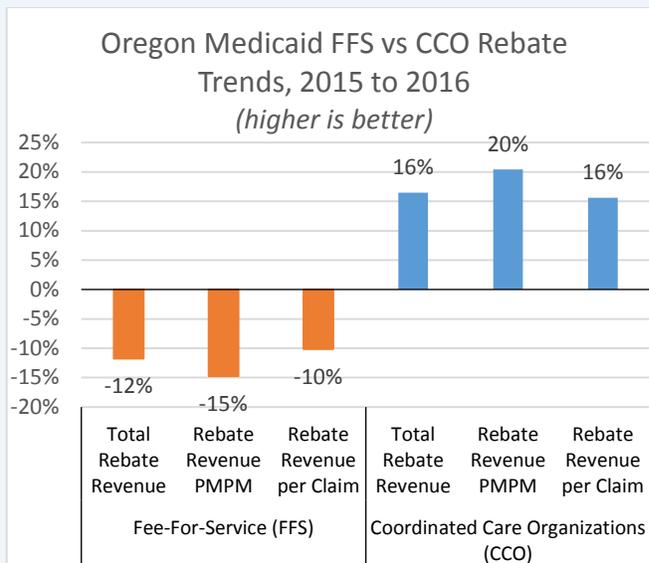
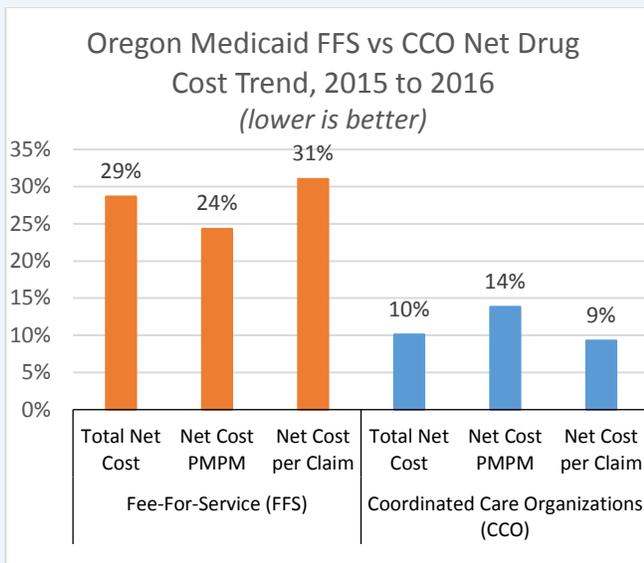
Pharmaceutical costs are the single largest driver of cost increases in OHP over the past five years. From 2015 to 2016 the Oregon Medicaid net pharmacy costs increased by 9.1%. In response to this funding crisis, some are calling for a uniform state-mandated preferred drug list (PDL) to align Coordinated Care Organization (CCO) PDLs with the Fee-For-Service (FFS) PDL.

Background

1. **Pharmaceuticals drive increasing health care costs across the nation.** Prescription drug costs are the fastest growing segment of U.S. health care spending, rising at 10 times the rate of inflation.
2. **Changes in drug mix drive increasing pharmaceutical costs.** Pharmaceutical cost increases are driven by three forces: utilization increase (enrollees using more medications); inflation (unit cost increase); and drug mix (utilization shift from cheaper agents to more expensive agents). While all three factors are responsible for increasing costs in Oregon, the largest contributor is drug mix change. Providers are prescribing more expensive drugs, including specialty and professionally administered drugs (PAD). In the first half of 2017, less than 2% of prescriptions accounted for more than 50% of Oregon Medicaid pharmacy spend.
3. **State-mandated formularies produced negative results in other states.**
 - The four states requiring Medicaid Managed Care Organizations (MCOs) to utilize uniform PDLs were collectively above the national average in net cost per prescription. Average net costs per prescription across these states during 2014 were 5% above the Medicaid national average. Florida experienced a 45% increase in overall plan drug costs after implementing a uniform state-mandated PDL, which was largely driven by a 49% increase in brand drug costs and a 13% decrease in generic utilization.
 - State-mandated PDLs have the unintended consequences of negatively affecting drug mix by driving up the use of more costly drugs. Allowing CCOs to manage drug mix based on local prescribing patterns and population health initiatives yields significant savings while maintaining quality care.

Assessment

1. **A uniform state-mandated PDL is a poor solution to this problem.**
 - A PDL's ability to effectively manage drug mix is assessed by measuring net drug cost rate of increase (trend) year-to-year. When comparing the FFS and CCO net drug cost trend from 2015 to 2016, CCOs have a lower net drug cost trend as illustrated by the following graph (below, left).
 - It has been speculated that a state-mandated PDL will improve rebate revenue because the Oregon P&T Committee has access to federal rebate rates and is able to factor this into the FFS PDL. However, in 2016, federal rebates resulted in a 43.6% discount off gross FFS claim costs and 48.5% off gross CCO claim costs, meaning CCO claims are generating federal rebates at a higher rate than FFS claims. Additionally, from 2015 to 2016 total rebate revenue, rebate revenue PMPM and rebate revenue per claim, have increased for CCO claims and decreased for FFS claims as illustrated by the following graph (below, right).



Recommendation

A uniform state-mandated PDL is not an effective strategy for controlling pharmaceutical costs and would be especially detrimental in Oregon. We do not recommend proceeding with this approach and have outlined alternative strategies below:

1. **Improve FFS and CCO collaboration.** Expanding the Oregon Pharmacy & Therapeutics Committee to allow more CCO representation would improve collaboration and sharing of best practices. Additionally, the ability to collaborate on pricing arrangements would also be advantageous to CCOs and FFS. These could be through group supplemental rebate agreements or 340B arrangements for CCOs who choose to participate. Furthermore, Oregon should leverage the agility of CCOs to implement PDL changes quickly to shift utilization in response to drug price changes. FFS lacks the ability to respond quickly to market changes due to cumbersome legislative requirements.
2. **Deploy utilization management strategies for PADs.** PADs account for the fastest growing portion of pharmaceutical spend in Oregon due to high utilization of costly specialty drugs and minimal utilization management controls. Oregon P&T should leverage individual CCO efforts and subject matter experts to create statewide best practices.
3. **Further leverage lines 500 & 660 on the Prioritized List of Health Services to exclude payment for high cost, marginal benefit drugs.** In order to methodologically review new and existing treatments for appropriate placement on these lines, we recommended that a robust set of objective criteria be developed. This will facilitate a more streamlined, evidence-based approach. The Health Evidence Review Commission should leverage pharmacist expertise by adding CCO pharmacist positions to the committee.
4. **Remove barriers to FFS utilization management.** Eliminate the “provider prevails” policy and modify legislative requirements preventing timely FFS PDL changes.
5. **Decrease medication waste.** Efforts promoting deprescribing and improving medication adherence can effectively combat medication waste to decrease spend and improve health outcomes. Waste can include utilization of medications that lack evidence of producing better health outcomes compared to less-expensive alternatives, inefficiencies in the prescribing and dispensing process (duplicative therapy, excessive dose or duration of therapy, etc.), and costs incurred while treating adverse drug events.

INTRODUCTION

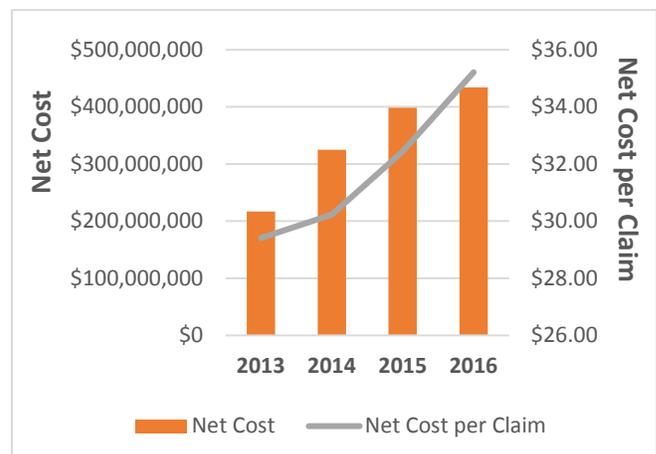
Prescription drug costs are the fastest growing segment of U.S. health care spending. Prescription drug prices have skyrocketed in the United States, rising at 10 times the rate of inflation (1). With the continued release of new and expensive therapies, state Medicaid programs are under increasing pressure to provide access to these drugs, while managing competing priorities and program budgets. As states' recent experiences with new hepatitis C drugs illustrate, soaring costs of specialty drugs have exceeded Medicaid budgets, forcing state agencies to request additional funding from their legislatures, straining allocation of public resources, and putting other programs at risk (2). Pharmaceutical costs are the single largest driver of cost increases in OHP over the past five years. Furthermore, the approval of the 21st Century Cures Act in 2016 gave the Food and Drug Administration (FDA) more discretion in the kinds of evidence and clinical studies it requires to evaluate new medications for approval. As a result, it is expected that there will be an increasing number of new high-cost medications approved with limited evidence of clinical benefit. It is more important than ever for CCOs to have the liberty to leverage every tool at their disposal to rein in drug costs.

In response to this pharmacy-funding crisis, some are calling for a uniform state-mandated preferred drug list (PDL) to align Coordinated Care Organization (CCO) PDLs with the Fee-For-Service (FFS) PDL. Drugs placed on the PDL can be prescribed without authorization. Enrollees can still access non-preferred drugs, but only through prior authorization from the CCO. Some hope that this effort will maximize federal rebate monies and decrease the rate of pharmacy spending. However noble the intent, this proposal is misguided and will have disastrous results in Oregon. This paper will methodologically examine the root cause for the rise in pharmaceutical spend in order to determine the best approach to manage costs. We will also look at other states that have moved to a uniform state-mandated PDL to study the effects of this change in order to predict the outcome of this initiative in Oregon. Lastly, we will recommend alternative approaches to manage drug costs successfully without detriment to Medicaid enrollees.

FORCES DRIVING INCREASES IN OREGON MEDICAID PHARMACEUTICAL SPEND

Oregon, along with nearly every Medicaid, Medicare and Commercial plan across the nation, has experienced huge increases in pharmaceutical cost in recent years. From 2015 to 2016 the Oregon Medicaid net drug costs increased by 9.1%. After accounting for changes in membership and claim volume, the net cost per member per month increased by 11.7% and the net cost per claim increased by 8.5% (3) (4).

The root cause of this problem is changes in drug mix. Drug mix is a term used to describe the type of drugs used by a population. Pharmaceutical costs are impacted by three forces: utilization increase (enrollees taking more medications); inflation (the unit cost of a drug increasing); and drug mix (enrollees shifting from cheaper drugs to more expensive drugs). While all three factors are responsible for increasing costs in Oregon, the largest contributor is changes in drug mix. **Providers are prescribing new more costly agents, including high-cost specialty and provider administered drugs (PAD). In the first half of 2017, less than 2% of prescriptions accounted for greater than 50% of Oregon Medicaid pharmacy spend (5).**



Specialty drug utilization soars

Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions like cancer, rheumatoid arthritis and multiple sclerosis. The Medicaid and CHIP Payment and Access Commission (MACPAC) reported double-digit increases in outpatient prescription drug spending in 2014 and 2015, attributable to increase in specialty drug utilization, specifically drugs used to treat Hepatitis C (6). Similarly, the 2017 Magellan Rx Medicaid Pharmacy Trend Report notes a large increase in specialty drug spend and modest decrease in traditional (non-specialty) drug spend from 2015 to 2016 (7). For the first half of 2017, specialty drugs accounted for less than 1% of the prescriptions filled and 39% of Oregon Medicaid pharmacy costs (8). By 2019, it is estimated that specialty drugs will account for half of a plan's total pharmacy spend (9). It is essential for Oregon to aggressively manage specialty drug utilization in order to contain costs.

Professionally administered drug (PAD) use is on the rise

A drug may be covered under the prescription drug benefit if it is self-administered or under the medical benefit if it is administered by a health care provider via infusion or injection (AKA Professionally or Physician Administered Drug, PAD for short). When a health care professional administers a PAD, this can create a conflict of interest, because the health care professional can profit greatly from the furnishing and administration of these drugs. Pharmaceutical manufacturers can successfully increase their products market share through efforts to increase provider prescribing. In 2016, the FDA approved a record-setting 45 novel medications besting its ten-year average approval rate of 28 novel drugs per year. Thirteen of these new drugs were PADs (10).

The 2016 Magellan Rx Medical Pharmacy Trend Report states that approximately 50 percent of the annual specialty drug spend were PADs billed under the medical benefit (10). In Oregon, Medicaid gross drug costs for PADs are increasing at twice the rate of drugs provided under the pharmacy benefit (referred to as Physical Health Drugs or PHD by Oregon P&T) as illustrated by tables 1 through 3 below (3) (4).

Table 1: Oregon Medicaid Gross Drug Costs (3) (4). Professionally Administered Drug (PAD) gross costs are rising faster than Mental Health Carve-out Drug (MHCD) gross costs and Physical Health Drug (PHD) gross costs.

	2015	2016	Trend*
MHCD*	\$130,959,403	\$105,339,798	-19.6%
PHD	\$542,518,189	\$601,001,781	10.8%
PAD	\$107,643,901	\$131,028,983	21.7%

*FFS only

Table 2: Oregon Medicaid Drug Claim Volume (3) (4). PAD gross cost increase from 2015 to 2016 is primarily due to increased utilization.

	2015	2016	Trend*
MHCD*	1,810,337	1,817,183	0.4%
PHD	9,340,793	9,222,053	-1.3%
PAD	1,125,303	1,296,067	15.2%

*FFS only

Table 3: Oregon Medicaid Gross Drug Cost Per Claim (3) (4). *PAD and PHD gross cost per claim is increasing due to changes in drug mix (shift in utilization from less costly agents to more costly agents).*

	2015	2016	Trend*
MHCD*	\$72.34	\$57.97	-19.9%
PHD	\$58.08	\$65.17	12.2%
PAD	\$95.66	\$101.10	5.7%

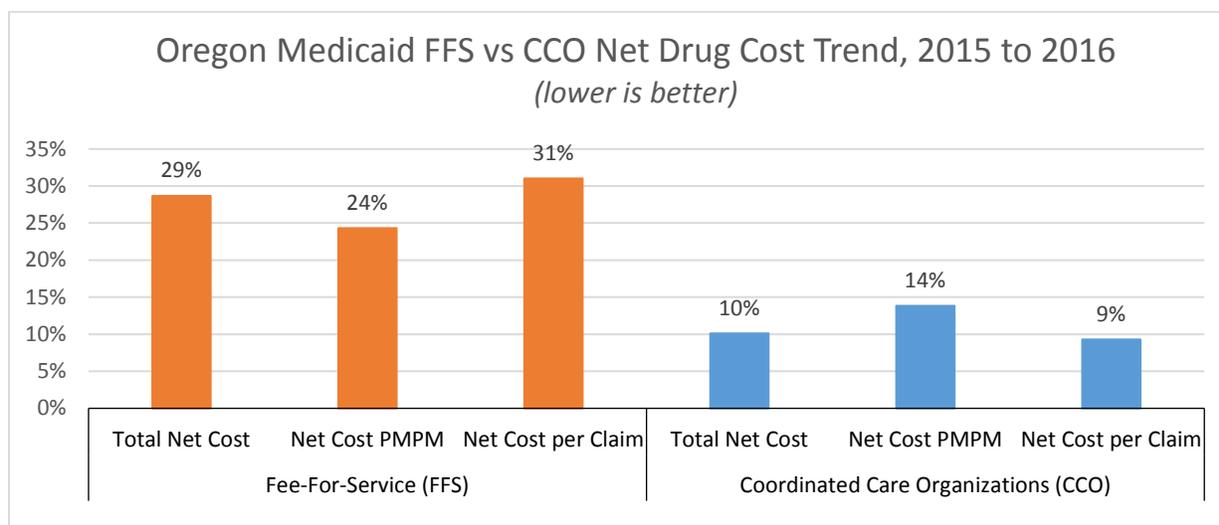
*FFS only

CCOs are more effectively containing costs through management of drug mix

Drug mix is a term used to describe the type of drugs used by a population. Pharmaceutical costs are impacted by three forces: utilization increase (i.e. enrollees taking more medications); inflation (the unit cost of a drug increasing); and drug mix (enrollees shifting from cheaper agents to more expensive agents). While all three factors are responsible for increasing costs in Oregon, the greatest driver is change in drug mix (3) (4).

Neither the prescriber nor the Medicaid recipient typically has a financial incentive to utilize relatively low-cost drugs. Significant copayment differentials are typically used in the commercial insurance and Medicare Part D settings to encourage patients to select relatively low-cost products. However, in Oregon Medicaid no copayment is charged whatsoever. Given these dynamics, the most important pharmacy cost containment tool available to CCOs involves optimal management of the mix of drugs, which means shifting utilization to more cost-effective drugs. A recent study indicated that the majority of the Medicaid savings derived through optimal management of the pharmacy benefit accrue through impacts on drug mix (11). Managing the mix of drugs used is accomplished purely through PDL management and other utilization management (UM) strategies such as prior authorization and step therapy criteria (requiring lower-cost agents before higher-cost agents).

A PDL’s ability to effectively manage drug mix is assessed by measuring the rate of increase of net drug costs year-to-year (trend). When comparing FFS and CCO net drug cost trend from 2015 to 2016, CCOs have a lower net drug cost trend as illustrated by the graph below (mental health carve-out drugs were excluded from this analysis to ensure parity). From 2015 to 2016, average net drug cost per FFS enrollee has increased at a rate nearly two times higher than average net drug cost per CCO enrollee (24% vs 14%). Average net cost per claim is more than three times higher for FFS claims compared to CCO claims (31% vs 9%) (3) (4).

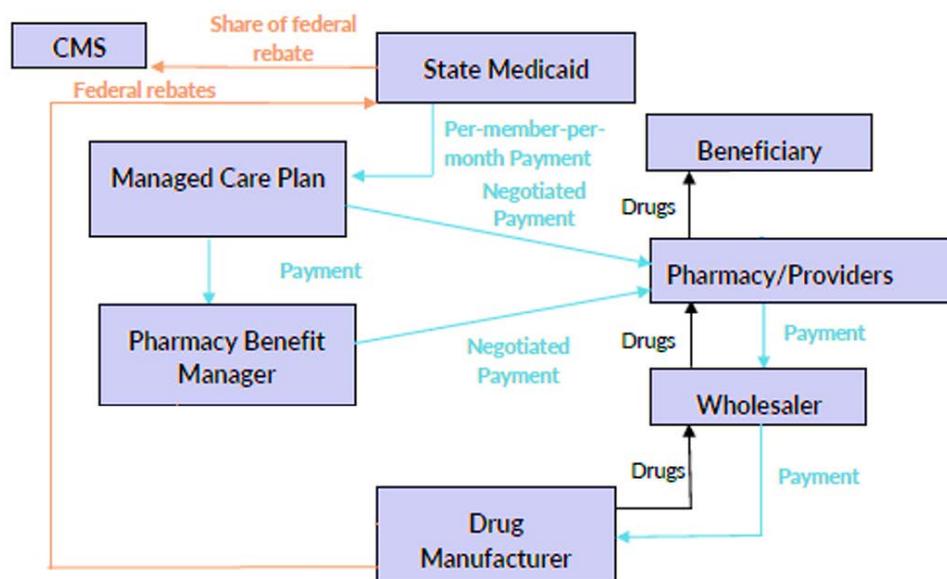


CCOs are better able to manage drug utilization because they have the latitude to quickly address local utilization and prescribing trends through their PDL and utilization management (UM) criteria. CCOs also have greater insight into the regional factors affecting the health of the population they serve. A PDL integrates with the overall population based strategy to care for a community and must remain flexible to meet the needs of various quality projects that are often informed by outcome metrics.

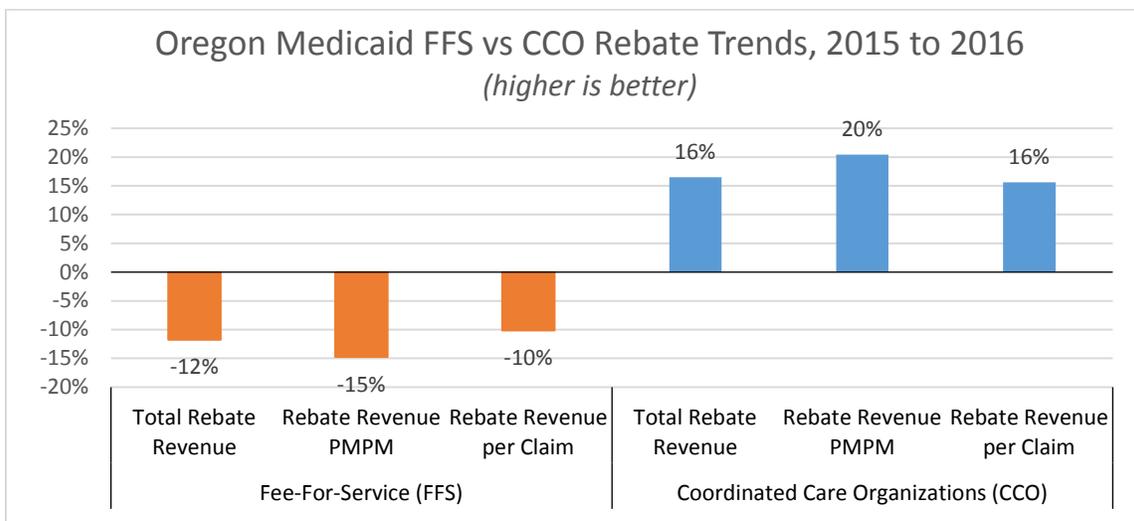
Additionally, the Oregon P&T Committee is a public meeting where public comment is often dominated by pharmaceutical manufacturers. The Oregon State Drug Use and Research Management program conducts high quality evidence reviews, however PDL placement can still be influenced by pharmaceutical manufactures, advocacy groups that lack understanding of evidence-based medicine, and provider specialists practicing beyond the currently available published evidence. This introduces bias into the PDL decision-making process, which should be based entirely on high quality published evidence. It is not appropriate to utilize Oregonian taxpayer dollars for medical treatments that lack a substantial body of evidence supporting effectiveness for the specific population treated.

Decreasing federal rebate revenue is not responsible for the funding crisis in Oregon

Medicaid rebates are dysfunctional and extremely problematic, but they are not responsible for the funding crisis in Oregon and are not the solution. Some states have succumbed to the temptation to implement measures to maximize rebates, like controlling the PDL, which has the unfortunate and unintended consequences of lining the pockets of pharmaceutical manufacturers with taxpayer dollars. As illustrated by the figure below, the rebate system is dysfunctional and complex (12). Federal rebate rates are shrouded in secrecy, so that the managed care plan or CCO is prohibited from knowing net drug costs. Additionally, the state collects the federal rebates from pharmaceutical manufactures for claims paid by CCOs, but this revenue is not passed back to the CCOs that paid the claims in a direct, transparent process. While the state estimates federal rebate revenue when calculating future CCO capitated payments, there is a lag in this process and it places the financial risk of gross costs on the CCO. When a state starts considering rebates as a revenue stream, separate from the up-front “gross” costs paid by CCOs, this creates problems. When the state controls the PDL to maximize rebate revenue, this process is further corrupted, ultimately leading to coverage of more and more high-cost specialty and brand drugs over time, increases in CCO gross costs and capitated payments, and increases in pharmaceutical manufacturer profits.



We have established that maximizing federal rebates is not a productive long-term solution and will ultimately backfire to benefit pharmaceutical manufacturers. Despite this knowledge, if legislation was passed mandating Oregon CCOs use the FFS formulary in the misguided hope of increasing rebate revenue short-term, this would also backfire. To test the hypothesis that the FFS formulary generates increased rebate revenue, we compared FFS and CCO rebate yield. In 2016, federal rebates resulted in 43.6% discount off gross FFS claim costs and 48.5% off gross CCO claim costs, meaning CCO claims are generating federal rebates at a higher rate than FFS. Additionally, from 2015 to 2016 total rebate revenue, rebate revenue PMPM and rebate revenue per claim, have increased for CCO claims and decreased for FFS claims as illustrated by the graph below (mental health carve-out drugs were excluded from this analysis to ensure an equitable comparison). This raises concerns that a uniform state-mandated PDL will negatively impact rebate revenue in Oregon.



Additionally, table 4 below shows mental health carve-out drug (MHCD) mix changes are largely responsible for decreased rebate revenue from 2015 to 2016. Mental health drugs are carved-out of CCO coverage, meaning they are covered and managed exclusively by FFS.

Table 4: Total Oregon Medicaid Rebate Revenue (FFS and CCO combined). From 2015 to 2016, Mental Health Carve-out Drug (MHCD) rebate revenue decreased significantly (-30.5%).

	2015	2016	Trend*
MHCD*	\$73,187,822	\$50,886,319	-30.5%
PHD + PAD	\$309,690,437	\$352,125,553	13.7%

* FFS only

HOW STATE-MANDATED FORMULARIES IMPACT COSTS IN OTHER STATES

Pros and cons of a uniform state-mandated PDL

Nine priorities that have often been cited when discussing arguments for and against a uniform state-mandated PDL. The following table summarizes these arguments (13).

Priorities	Arguments in favor of a single Medicaid PDL	Arguments opposed to a single Medicaid PDL
Administrative Ease	A single Medicaid PDL will improve ease of prescribing for prescribers who see Medicaid enrollees from multiple CCOs and FFS. These prescribers will know what drugs are covered under the PDL.	There are multiple commercial and Medicare Part D plans within any given community that prescribers, pharmacies and patients must navigate. Consolidating Medicaid formularies will have minimal or no impact on administrative ease for the vast majority of the prescribing community. It is also important to note that information technology is greatly improving access to various PDLs to streamline the prescribing process.
Consistent Access	With a single Medicaid PDL, all Medicaid beneficiaries have comparable access to the same set of medications.	The purpose of the CCO model is to adapt health care benefits to meet the unique needs of the community. A uniform PDL is out of alignment with this principle. Medicaid CCO beneficiaries have consistent access to medications provided within a more fully coordinated care model.
Rebate Maximization	A single Medicaid PDL drives more volume to certain brand medications where the percentage rebate is highest. In some instances, these rebates can result in the net (post-rebate) cost for the brand drug being lower than most or all generic alternatives.	The pursuit of maximum rebates is counter-productive to achieving the lowest net cost for the medications prescribed. This strategy benefits pharmaceutical manufacturers. Additionally, as described earlier in this report, Oregon CCO claims are generating more rebate revenue per claim than FFS claims. This proposed advantage would very likely not be achieved in Oregon through a single state-mandated PDL. 340B pharmacy claims are excluded from the drug rebate process to prevent double payment from the drug manufacturers, therefore, 340B pharmacy claims reduce the amount of rebate revenue the state can generate on rebatable drugs. Leveraging 340B drug pricing is a valuable strategy for managing pharmacy costs, however, a single PDL will limit the flexibility of 340B eligible entities to utilize medications that are most cost-effective for their patients and the health plans that serve them.
Volume Purchasing	Improving the purchasing power of our state by joining a large drug-purchasing pool like OPDP will result in savings, contingent on an aligned PDL.	While it appears that having a large purchasing power may be of some benefit, leveraging purchasing power tends to be a price-focused strategy . As discussed above with the rebates, this general approach is not as effective as managing the mix of drugs which is evident when comparing net cost per member of larger states vs smaller states, or smaller CCOs vs larger CCOs. Additionally, consolidating CCOs under one PBM would decrease competition , lessening pressure on PBMs to keep pharmacy rates low.
Minimizing Politicization		A uniform PDL at the state level allows drug manufacturers to achieve successful product placement by introducing bias and confounding information into the public P&T PDL decision process. A uniform state-determined PDL is likely to be overly inclusive of high-cost products that are not delivering adequate clinical value in return for their often large cost difference. Comparison of drug mix between the Medicaid FFS and Medicaid MCO or CCOs across the US strongly support this argument.

Priorities	Arguments in favor of a single Medicaid PDL	Arguments opposed to a single Medicaid PDL
Overcoming Lack of Co-Pay Barrier		With the large price differentials and without meaningful copayments or copayment differentials, there simply is no mechanism within a uniform and broad statewide Medicaid PDL to prevent unnecessarily high-cost medication utilization. CCOs latitude to enforce use of the lowest-cost, clinically appropriate medication is a critical and often the only means of achieving cost-effective prescribing practices.
Optimizing Cost Savings		The Medicaid program experiences unnecessarily high net pharmacy costs due to the loss of the ability to guide evidence-based prescribing. Wide price differentials exist between clinically effective medication options and between prescribing practices in a community. A CCO's ability to steer volume to the lower-cost therapy is crucial.
Integration of Complex Priorities		The arguments for a uniform state-mandated PDL suggest that the Medicaid pharmacy benefit operates in a silo. However, medication coverage is interwoven into broader health care needs. A state-mandated PDL does not allow CCOs the flexibility to best balance the wide array of priorities associated with "whole person" care coordination for large and diverse populations. Uniform state requirements do not allow CCOs the flexibility to be innovative and is against the founding principles of the Oregon CCO model.
Enrollee Disruption		More than 86% of Oregon Medicaid membership were enrolled in a CCO in 2016. Transitioning these members to the FFS PDL would cause significant disruption in prescription drug coverage. Members would be required to switch therapies resulting in disruption of therapy and a huge administrative burden on the prescribing community as well as the CCOs to process the prior authorization requests. Grandfathering to allow enrollees to continue on their current medications has been proposed as a solution to this problem. However, this will greatly increase pharmaceutical costs and is challenging to operationalize.

In assessing the arguments for and against a single PDL, the arguments against a single PDL are both more numerous and more compelling than the arguments for adopting a uniform state-mandated PDL. Thus, allowing CCOs to continue managing their PDLs appears to be the most constructive policy stance for Oregon to adopt. In managing the drug mix as they view most appropriate, CCOs are best able to perform their role of maximizing the clinical effectiveness and cost-effectiveness of Medicaid coverage.

Oregon must learn from the experience in other states

In a 2016 analysis by the Menges group, they reported a handful of states require Medicaid MCOs to utilize the FFS PDL, including Florida, Kansas, Texas and West Virginia. These states were collectively above the national average in net cost per prescription. Average net costs per prescription across these states during 2014 were 5% above the US average (14). They concluded that a uniform state-mandated PDL impedes the MCO's ability to manage prescription drug benefits through establishment of clinically based formulary and utilization management tools promoting the use of generic drugs and cost-effective brand-name drugs when

appropriate. Published research analyzing the effect of a uniform state-mandated PDL are limited, but we have included the results of studies performed in two states below. Several states have moved to a uniform PDL since this analysis was published in 2016, and within the next few years we expect there will be more available literature in this area.

- **Florida:** According to an analysis conducted by Express Scripts Lab, when Florida implemented a uniform state-mandated PDL, drug utilization declined, yet plan costs increased. This was mainly driven by changes in drug mix including decreases in generic utilization and increases in brand drug utilization. They experienced a more than 45% increase in overall plan drug costs in the post-policy period, which was largely driven by a 49% increase in brand drug costs and a 13% decrease in generic utilization (15).
- **Texas:** A 2016 report prepared by the Menges Group for the Texas Association of Health Plans argues that substantial savings would accrue to the state if flexibility were given to the Medicaid managed care organizations, citing the plans' ability to negotiate net prices that are lower than the state's price with supplemental rebates factored in. They again conclude that favorable net prices are achievable by plans optimizing the mix of drugs. The authors state that Texas would achieve \$100 million in annual general fund savings if it rescinded the unified PDL requirement (16).

In summary, state-mandated formularies could have the unintended consequences of negatively affecting drug mix by driving up the use of more expensive drugs over less costly alternatives which will further increase Medicaid pharmacy spend in Oregon. Managing drug mix effectively yields significant cost savings at no clinical detriment, and it is important for states, including Oregon, to allow this to occur.

OREGON NEEDS ALTERNATIVE SOLUTIONS THAT WILL WORK

Solutions to the pharmacy funding crisis must address the root cause of the problem. A uniform state-mandated PDL will exacerbate the problem. The following are alternative solutions that will work.

Improve FFS and CCO collaboration

Oregon Medicaid would benefit by expanding the Oregon P&T Committee to allow for majority representation from CCOs. **We recommend legislation be changed to allow more CCO P&T committee representation.** CCOs have deployed various successful utilization management strategies within their communities to manage drug mix without clinical detriment. A forum that promotes the sharing of utilization management best practices and population health initiatives would be beneficial.

Adding additional CCO pharmacist positions to the Health Evidence Review Commission would increase the Commission's ability to leverage medication experts to optimize appropriate medication utilization.

Normalize 340B revenue flow across the state

FFS has 340B contractual arrangement with FQHCs that require all savings to be passed through. CCOs generally are only able to benefit from a portion of the 340B savings. The ability to collaborate on pricing arrangements would also be advantageous to CCOs and FFS. This could be in the form of group supplemental rebate agreements or 340B arrangements for CCOs who choose to participate. This collaboration would be mutually beneficial to 340B eligible entities, FFS, and CCOs.

Deploy utilization management strategies for PADs

The Oregon P&T Committee has traditionally applied minimal utilization management criteria to PADs. **We encourage CCOs and Oregon P&T to focus efforts in this area and form a workgroup to develop utilization management and best practice recommendations.** We encourage Oregon P&T to employ subject matter experts as consultants to advise on challenging classes of drugs, such as oncology.

We recommend development of statewide site-of-care guidelines that would drive PAD utilization to less costly sites of care or self-administered drugs when appropriate. These guidelines should also contain medical necessity criteria to ensure appropriate utilization and prevent inappropriate prescribing stemming from financial conflicts of interests.

Further leverage lines 500 & 660 for high cost, marginal benefit drugs

In recent years, numerous medications have come to market with limited or no evidence of a clinical benefit and annual prices ranging from tens of thousands to over one million dollars. This is the result of the passage of the 21st Century Cures Act in 2016 that gave the Food and Drug Administration (FDA) more discretion in the level of evidence and clinical studies it requires to evaluate new medications for approval. It is expected that there will be an increasing number of new medications approved with limited evidence of a clinical benefit and with very high annual cost. Examples of medications recently approved in each of these categories include Exondys 51 and Emflaza, respectively. Both of these medications are used to treat a rare type of muscular dystrophy. The FDA-labeled indication for Exondys 51 specifically states that “a clinical benefit of Exondys 51 has not been established.” For Emflaza, there is no clinical evidence demonstrating superior efficacy compared to prednisone; however, Emflaza is 1,000 times the cost of prednisone.

Effective 1/1/18, the Prioritized List has two new lines relating to the prioritization of services with marginal clinical benefit and/or low cost-effectiveness (line 500) and those with no clinically important benefit or that have harms that outweigh benefits (line 660). Recently, the Oregon P&T and Health Evidence Resource Commission (HERC) were able to place Emflaza and Exondys 51 on these lines, essentially excluding coverage of these medications under Medicaid. By definition, these two drugs were arguably the most ideal candidates for placement on these lines. However, this was an uphill emotional battle met with great resistance from pharmaceutical manufacturers, patient advocates, and specialist providers. This raises concerns that further efforts of HERC and Oregon P&T to utilize these lines based on objective unbiased evidence will be thwarted by outside parties with conflicting or misguided interests.

In order to methodologically review new and existing treatments for appropriate placement on these lines, we recommended that a robust set of objective criteria be developed. This will facilitate a more streamlined, evidence-based approach and transition subjective terms into objective measurements.

Remove barriers to utilization management

OHA should change legislation to eliminate FFS “provider prevails” policies that require coverage of non-preferred drugs in cases when a provider does not give rationale of why preferred drug alternatives are not appropriate. **This policy is detrimental to drug mix management efforts and we recommend removing this requirement as soon as possible.**

Additionally, current legislative requirements prevent the Oregon P&T from implementing timely changes to the FFS PDL. For example, it can take up to 90 days for P&T recommendations to be reflected in the FFS PDL resulting in lost savings. **We recommend legislative changes to allow more expedient FFS PDL updates.**

Decrease medication waste

One powerful way to rein in escalating pharmaceutical spend without impacting health outcomes is to **implement efforts to control waste**. Waste can include utilization of medications that lack evidence of producing better health outcomes compared to less-expensive alternatives, inefficiencies in the prescribing and dispensing process (duplicative therapy, excessive dose or duration of therapy, etc.), and costs incurred while treating adverse drug events.

We can effectively **combat waste through deprescribing efforts** to support health care providers and patients in reducing or stopping medications that may be harmful or no longer needed. Deprescribing is the planned process of reducing or stopping medications that may no longer be needed and that may be causing adverse drug events. The goal is to reduce polypharmacy while improving quality of life and decreasing medication burden or harm.

Efforts to improve medication adherence go hand-in-hand with deprescribing. Many patients who appear non-adherent to therapy may have complicated medication regimens that introduce barriers to optimizing treatment outcomes. By deprescribing and simplifying regimens to meet patient needs and improve adherence, patients will achieve better outcomes and we will reduce spending on ineffective and unnecessary treatments.

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Co-signatures:

