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Policy Evaluation: HB 2126 – Oregon Health Plan Preferred Drug List Enforcement and Voluntary Mental Health Preferred Drug List

HB 2126[1] was passed in the 2009 Oregon Legislature. It specifically allows the Oregon Health Authority to require prior authorization (PA) for Oregon Health Plan fee-for-service drugs not listed as preferred on the Preferred Drug List (PDL), also called the Practitioner Managed Prescription Drug Plan. There are several significant exceptions to the State's ability to require prior authorization for PDL placement:

1) mental health (MH) drugs are not subject to prior authorization
2) provider prevails; meaning the Oregon Health Authority cannot deny access to the non-preferred product if the prescriber requests a prior authorization and after consultation deems the non-preferred drug medically necessary,
3) grandfathering; meaning the original prescription is written prior to July 1, 2009 or the request is for a refill for seizures, cancer, HIV or AIDS; or an immunosuppressant,
4) a prior authorization is not responded to the prescriber within 24 hours
5) the drug is in a class not reviewed for the PDL.

A budget reduction of approximately $4 million in Oregon Health Plan drug costs (total funds - TF) for the 09-11 biennium was assigned to this bill. This budget target assumes 90% use of preferred products and a January 1, 2010 start date. Another $3 million (TF) was assigned to a voluntary mental health PDL.

HB 2126 mandates Oregon Health Authority report to the health related committees and the Joint Committee on Ways and Means of the Seventy-sixth Legislative Assembly on the implementation and effectiveness. This evaluation is an update of the preliminary evaluation done in January 2011[2] and will determine if HB 2126 budget targets were achieved, if target use rates of preferred products were realized, report on prior authorization requests made, approved and time to respond and highlight opportunities for improvement.

History of Oregon Health Plan PDL implementation

The Oregon Health Plan PDL was initially authorized by the 2001 Legislature.[3] The legislation mandated that drugs be publicly evaluated first for their clinical evidence and second for their relative cost. The Oregon Health Plan PDL is created using a combination of evidence from the medical literature and local clinician opinions. This is different from an insurance company formulary development because public comment is embedded at several locations in the process and the evidence evaluation is done using established, explicit and transparent standards.[4, 5] See Appendix A for a flow chart of the current PDL development process.

Drug cost is considered only after clinical recommendations are made. The net price includes two types of manufacturer rebates. CMS[6] mandated rebates, which are a condition of Medicaid participation, and Supplemental Rebates, which are negotiated in addition to the CMS Rebates. Supplemental Rebates are not *required* to be considered for PDL preferred status but are *considered* in the pricing. Both rebates

are proprietary and confidential and cannot be disclosed. See Figure 1 for an example of how rebates affect net price of brand and generic drugs. The base price per unit is based on the average cost per day of a brand drug and a generic drug. This model assumes a 30% CMS brand rebate, 13% generic CMS rebate, 3% brand supplemental rebate and 0% generic supplemental rebate. However, there is great variance in all of these costs and rates across the market.

Figure 1

Brand Drug Rebate Example

$11.30	Price per unit reimbursed to pharmacy by Oregon Health Authority
- 3.40	Less CMS rebate per unit paid by manufacturer to Oregon Health Authority for each unit reimbursed
$ 7.90	Net cost with CMS rebate
- 0.25	Less supplemental rebate per unit paid by manufacturer to Oregon Health Authority for each unit reimbursed
$ 7.65	Final Net-Net Cost per unit

Generic Drug Rebate Example

$ 1.70	Price per unit reimbursed to pharmacy by Oregon Health Authority
- 0.10	less CMS rebate per unit paid by manufacturer to Oregon Health Authority for each unit reimbursed
$ 1.60	Net cost with CMS rebate
- 0.00	Less supplemental rebate per unit paid by manufacturer to Oregon Health Authority for each unit reimbursed
$ 1.60	Final Net-Net Cost per unit

Supplemental rebates were rarely offered to Oregon by individual manufacturers prior to July 1, 2009 when the Oregon Health Authority contracted with the Sovereign States Drug Consortium (SSDC)[7] to negotiate Supplemental Rebates with manufacturers. Many manufacturers require prior authorization of non-preferred drugs in return for Supplemental Rebates but rarely require market share guarantees. The SSDC is a non-profit, multi-state, Medicaid purchasing pool. The January 2010 PDL update was the first update to use the SSDC Supplemental Rebate bids to determine net price.

The practice of requiring prior authorization for non-preferred drugs is commonly used by commercial insurance plans, Medicare Part D plans and the great majority of state Medicaid programs in order to increase market share of the preferred drugs used. Increased market share of preferred drugs saves money through increased use of high quality, lower cost drugs and provides leverage to negotiate lower net prices (aka Supplemental Rebates) from manufacturers. The process to access non-preferred drugs has varied from 2002 to present. See Table 1 for a summary.

Table 1 – Oregon Health Plan PDL Implementation Summary

Period	Process to Access Non-Preferred Drugs	Preferred Drug Use Rate[8]	Comments
Aug 2002 - Apr 2003	"Dispense as Written" noted on prescription	58% (PH only)	Technically challenging to administer with claim system; did not meet budget targets
May 2003 - Sep 2003	Prior authorization	82% (PH only)	Avoided ~ $500,000TF/month[9] but the legislature prohibited prior authorization in subsequent special session
Oct 2003 - Feb 2008	Voluntary with targeted provider education and use of Epocrates[10]	68%-76% (PH only)	Difficult to leverage supplemental rebates
Mar 2008 – Dec 2009	Copay & quantity incentives; Epocrates	76% - 82% (PH only)	Increased preferred drug use, but still not meeting target 90%; No voluntary MH PDL;
Jan 2010 - Mar 2010	Copay & quantity incentives; Epocrates; Voluntary MH PDL added	74% (PH / MH combined)	Addition of MH drugs decreased overall preferred use rate. MH drugs influence the rate significantly due to the MH drug carve-out from managed care. They also have a lower preferred drug use rate. PDL developed with supplemental bids included
Apr 2010 – Dec 2010	Prior authorization started for physical health (PH) PDL[11]; Voluntary MH PDL (no prior authorization); Copay & quantity incentives continue; Epocrates	74% - 76% (PH / MH combined)	Grandfathering & provider prevails in place per statute; Some MH supplemental bids not available without prior authorization
Jan 2011 - Present	42 new PH classes added to the PDL. PA continues for PH PDL only. MH PDL remains voluntary	76% - 80% (PH / MH combined)	

TF = total funds, PH = Physical Health, MH=Mental Health, PDL = Preferred Drug List

Methods

The total gross drug cost trend was derived from paid, clean, fee-for-service drug claims and was reported as the sum of the amount paid on the claim. PDL status is the list effective on the date of dispensing.

Cost avoidance is a function of increased use of lower cost drugs at the pharmacy and increased rebate revenues. A pharmacy reimbursement trend analysis was done for a 15 month period before the prior authorization implementation and 17 months following implementation. The pre period was; 1/1/09 – 3/31/10 (15 months) and the post period was; 5/1/10 – 9/30/11 (17 months). The expected monthly linear trend was compared with observed monthly trend. The difference in trend estimated the cost avoidance. The trend analysis was conducted in aggregate, grouped by physical health (PH) and mental health (MH) drugs, on a per member per month (PMPM) basis to control for changes in enrollment. The PH drugs excluded hemophilia drugs because payment policy changed during the evaluation period and they are not included in the PDL.

A CMS rebate revenue trend analysis for a 12 month period prior to implementation of the new PDL and 6 months following implementation of the new PDL was planned. However, two confounders made this analysis impossible. The Affordable Care Act (ACA) changed the minimum rebate that must be provided by manufacturers beginning January 1, 2010 and changed the percentage of the rebate retained by the states. Supplemental Rebate revenue is entirely new revenue and thus is simply reported as revenue for the quarters claimed.

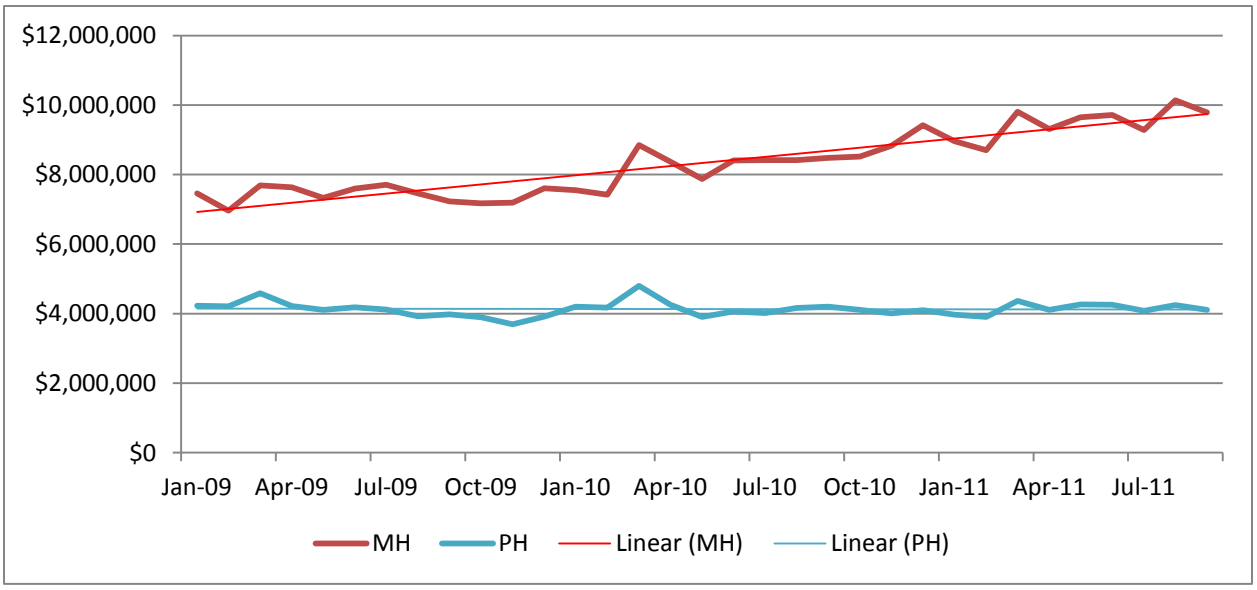
The preferred drug use rate was evaluated as the number of claims for preferred drugs over sum of the number of claims for both preferred and non-preferred drugs. This is reported as PA-enforced PH PDL and voluntary MH PDL separately.

Prior Authorization requests are reported by method of request and approval rate (i.e. number of prior authorizations approved divided by total prior authorizations requested).

Results

With the additional 42 classes added to the PDL January 1, 2011, the current Oregon Health Plan (OHP) PDL currently captures 78.5% of total OHP fee-for-service gross drug costs on average. The remaining 21.5% of costs are in classes that have not been reviewed for the PDL to date. The Voluntary MH PDL is associated with 60% of total OHP fee-for-service gross drug costs on average. This is because MH drugs are "carved-out" of Medicaid managed care contracts and thus all MH drugs for all OHP clients are paid for fee-for-service. Figure 2 displays that MH drugs continue to trend upwards at more than $1 million annually (14%). The PA-enforced PH PDL captures just 18.5% of total Oregon Health Plan fee-for-service gross drug costs and the trend is essentially flat.

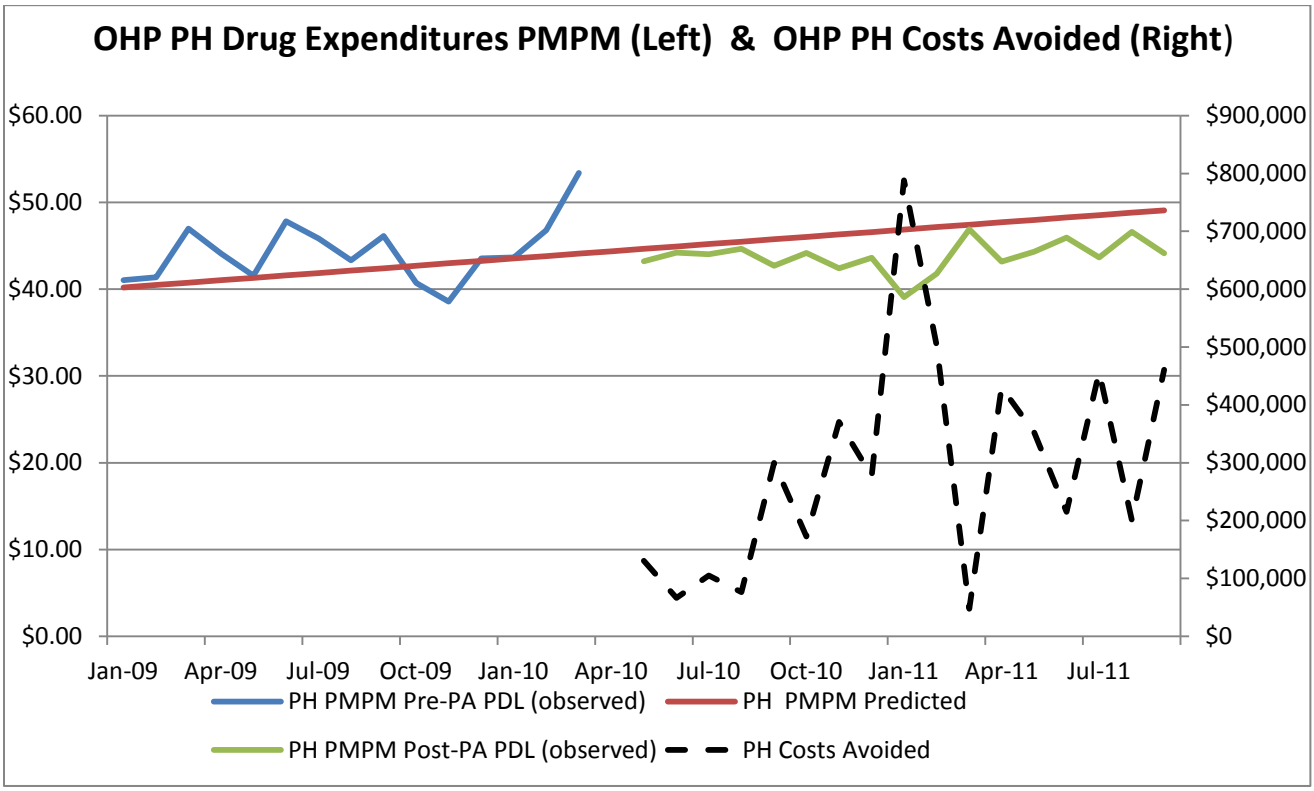
Figure 2 - Oregon Health Plan fee-for-service monthly gross drug cost trend[7]



PH = Physical Health; MH = Mental Health; Costs exclude all rebates

The trend analysis for the PA-enforced PH PDL expenditures PMPM is represented in Figure 3. Prior authorization enforcement was initiated April 13, 2010. For the first 17 months of the prior authorization enforcement an average of $291,000 per month was avoided. This is approximately $5 million total PH drug costs for the 17 months of evaluation and $3.8 million for the 14 months of the 09-11 biennia. However, it is likely that some of the savings in January 2011 should be attributed to a one-time change in pharmacy reimbursement implemented that month.

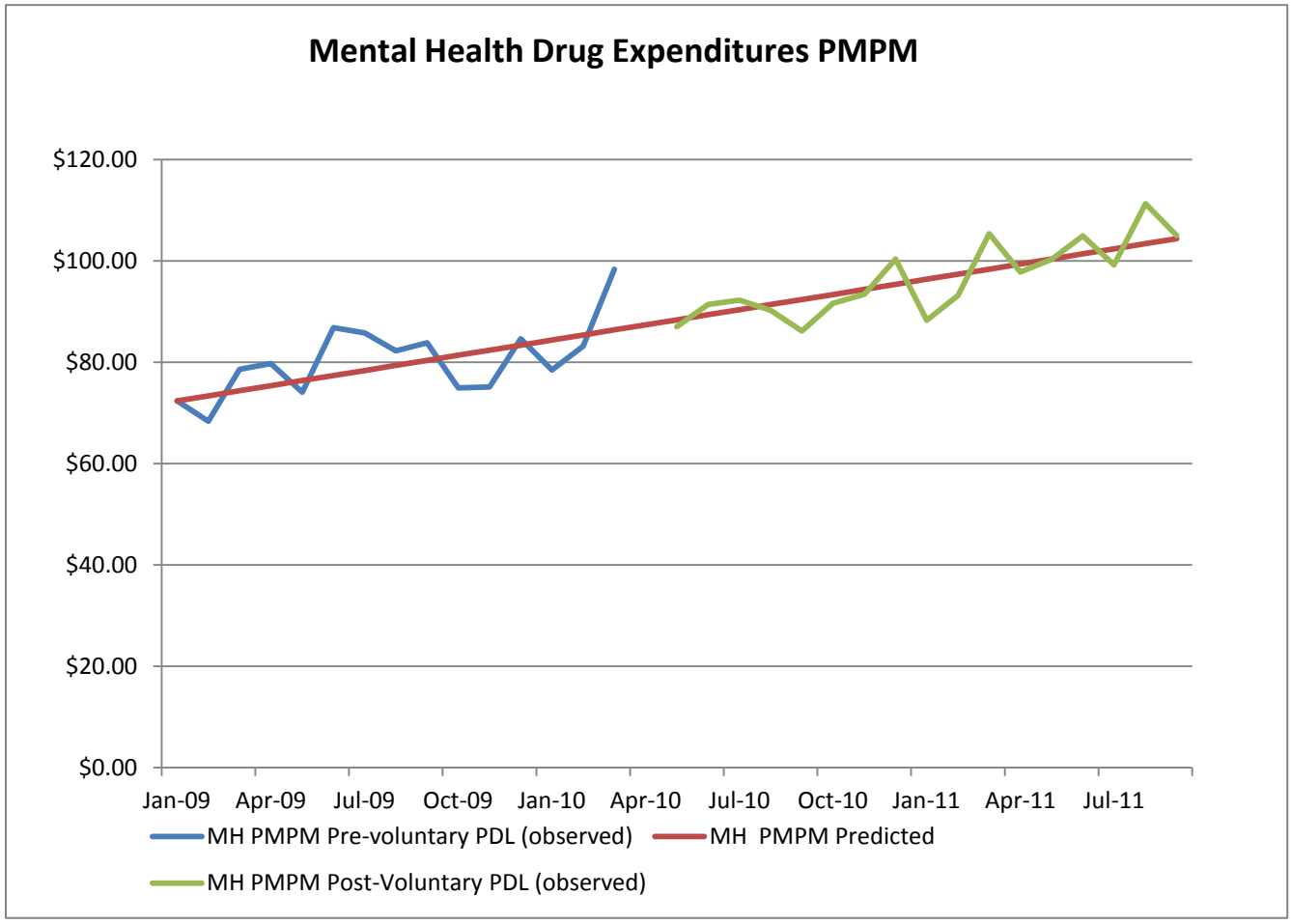
Figure 3 – Trend Analysis for PA-enforced PH PDL



PH = Physical Health; PMPM = per member per month; Costs exclude all rebates

The trend analysis for the voluntary MH PDL expenditures is represented in Figure 4. This group of drugs (60% of total FFS drug costs) is exempt from the prior authorization exception process and there is essentially no change in trend for the first 21 months (Jan 1, 2010 – Sep 30, 2011) of the voluntary MH PDL. Will there was a notable one-time effect from the January 2011 reimbursement change, the trend was not affected.

Figure 4 – Trend Analysis for Voluntary MH PDL



MH = Mental Health; PMPM = per member per month; Costs exclude all rebates

Prior to the SSDC[6] contract there were no supplemental rebate contracts in place. Calendar year Quarter 3 2009 was the first quarter of the new SSDC contract and invoices were prepared for the PH PDL in place at the time. Starting in Quarter 1 2010, the PH PDL was created using the supplemental bids and thus supplemental rebate revenues increased considerably from 1.5% to 3% of reimbursed PH PDL pharmacy costs. However, supplemental offers for branded drugs decreased dramatically in 2011 to 0.4% of reimbursed PH PDL pharmacy costs. This is likely due to the uncertainty created by the ACA and because many key drugs are going generic in 2011 and 2012.

There is an approximate 6-9 month delay from the time a drug is dispensed and paid for at the pharmacy to rebate collection. There is also considerable administrative burden to prepare contracts and invoices, track payments and settle disputes that is not captured in this analysis. Table 2 reports all the supplemental rebates collected for the PH PDL. There was $785,779 collected in the 2009-11 biennium since implementation of the PH PDL and with Quarter 2 2011 still outstanding.

Table 2 – Supplemental Rebates Invoiced for PH PDL Drugs

CY Quarter	Rebate Collected	Sum PH PDL Paid Claim Amount	Rebate Pct of PH PDL Costs
2009_3	$41,730	$3,197,885	1.3%
2009_4	$44,570	$2,994,814	1.5%
2010_1	$146,911	$4,477,253	3.3%
2010_2	$150,946	$4,021,537	3.8%
2010_3	$189,784	$4,091,650	4.6%
2010_4	$183,711	$4,056,110	4.5%
2011_1	$28,127	$7,231,306	0.4%

Table 3 reports MH drug supplemental rebate collections. There are several manufacturers of MH drugs that will not contract for supplemental rebates because there is no prior authorization in place for non-preferred drugs. Thus the collection rate for MH drugs is much lower (<0.3% of reimbursed MH PDL pharmacy costs). Two supplemental rebate bids for MH drugs that were not available to Oregon because of no prior authorization enforcement. These two bids amounted to almost $2.5 million for the 2009-11 biennia that went unrealized. Still, approximately $260,000 in MH drug supplemental rebates was collected in 2009-11.

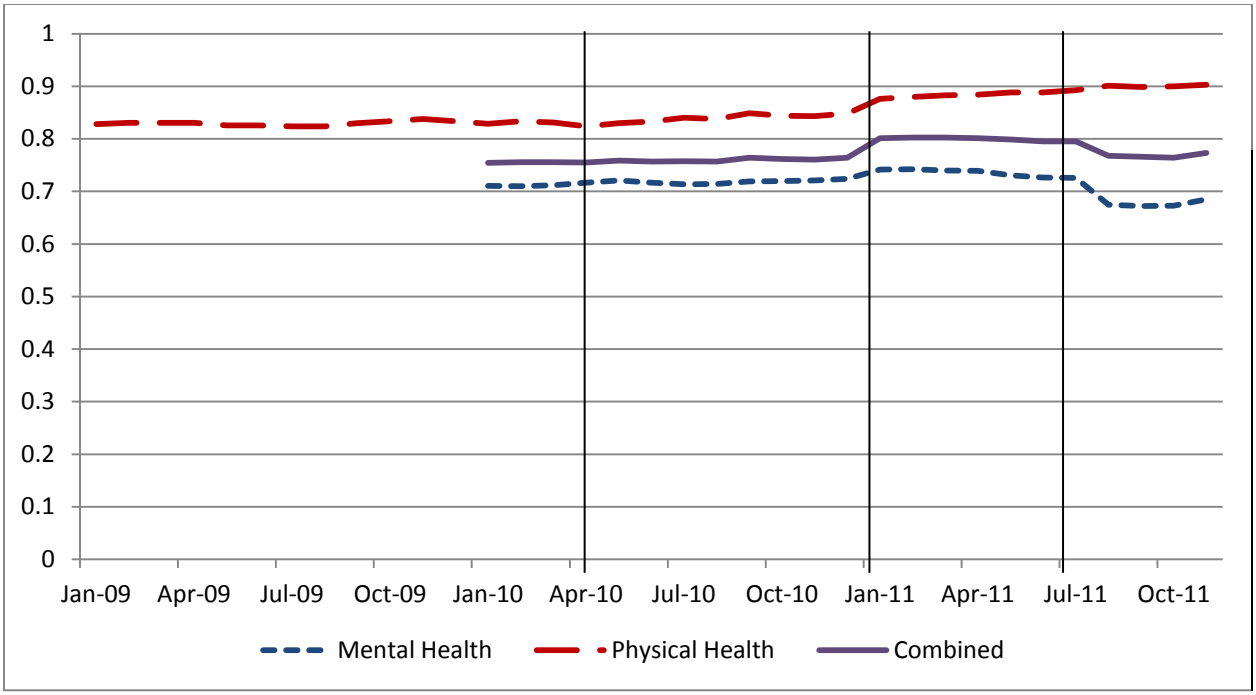
Table 3 – Supplemental Rebates Invoiced for MH PDL Drugs

CY Quarter	Rebate Collected	Sum MH PDL Paid Claim Amount	Rebate Pct of MH PDL Costs
2009_3			
2009_4			
2010_1	$43,978	$20,200,323	0.2%
2010_2	$67,448	$19,741,462	0.3%
2010_3	$69,319	$21,248,236	0.3%
2010_4	$45,682	$22,593,722	0.2%
2011_1	$33,858	$24,649,978	0.1%

Figure 5 depicts the preferred drug use rate for the PA-enforced PH PDL and the voluntary MH PDL. The pre-PA-enforced PH PDL preferred drug use rate was flat at 83%. The PA was implemented for the PH PDL in April 2010 with extensive grandfathering to accommodate patients that were stabilized on non-preferred drugs. Still, the preferred drug use rate of the PH PDL increased to 85% by July 2010. On January 2011 the PH PDL was revised accounting for an immediate increase to 87.5% preferred use rate and it has steadily increased to just over 90% in November 2011.

In contrast the voluntary MH PDL preferred drug use rate remained flat at 71% through 2010. It increased to 74% when with supplemental rebates that allowed two products be preferred through 7/1/2011 and decreased to 68% when both contracts were rescinded and those products were removed from the MH PDL.

Figure 5 –Rate of Preferred Drug Use for PH PDL, MH PDL and combined PDL



There are 72 drug classes captured by the PH PDL. Of these, 57 classes meet or exceed the target 90% preferred use rate. The preferred use rate for the remaining 15 classes is trending upward or has erratic utilization due to small numbers of claims.

HB2126 required that non-preferred prescriptions written prior to July 1, 2009 be exempt from prior authorization. To fulfill this mandate, the claims system was programmed to "grandfather" existing prescriptions for non-preferred drugs by generating and approving an "Auto-PA" for any client that had a paid claim for the non-preferred drug within the previous 90-days. The Auto-PA function was turned off in August 2010 when the statutory mandate had expired. Extensive grandfathering was also used to smooth implementation of 42 new classes in January of 2011. Table 4 reports the number of prior authorization requests made for non-preferred drugs by media type. Over 90% of prior authorizations

requested during the initial phases of prior authorization implementation were automatically generated and approved and this reflects the "grandfathering" policy. Both the total number of prior authorization requests and Auto-PA requests decline precipitously in September 2010 and April 2011 but there is not a consequent increase of other forms of prior authorization requests of similar magnitude. This change is also reflected in Figure 3 where the cost avoidance in September and October 2010 increases relative to previous months. Some non-preferred PDL drugs also have appropriate use prior authorization requirements imposed by Pharmacy and Therapeutics Committee recommendation that apply. This data does not differentiate between "appropriate use prior authorization" and "non-preferred drug prior authorization".

Table 4 - Total Non-Preferred Drug PAs Requested by Media Type

Total Non-Preferred Drug PAs								
Month	AUTO PA	ELEC TXN	FAX	ONLINE	PAPER	PHONE	WEB	TOTAL PA's ADJUD.
2010_01	103	0	30	5	0	38	0	176
2010_02	377	0	31	5	0	40	1	453
2010_03	257	0	57	4	0	53	1	371
2010_04	4,225	0	62	1	0	72	3	4,360
2010_05	1,822	1	71	3	0	50	6	1,947
2010_06	828	2	76	0	0	47	5	953
2010_07	1,023	0	44	0	0	56	4	1,123
2010_08	829	0	76	0	0	61	4	966
2010_09	37	0	97	1	0	101	12	236
2010_10	31	0	113	1	0	88	3	233
2010_11	26	0	86	1	0	77	5	190
2010_12	29	0	67	0	0	74	5	170
2011_01	5,748	0	148	5	1	170	14	6,072
2011_02	2,254	0	132	1	0	146	11	2,533
2011_03	1,580	0	171	1	1	122	15	1,875
2011_04	964	0	115	2	0	148	12	1,229
2011_05	388	1	246	3	0	238	21	876
2011_06	118	0	215	0	1	201	21	535
2011_07	206	0	128	1	0	143	11	478
2011_08	271	0	206	4	1	183	18	665
2011_09	89	0	153	4	0	154	13	400
2011_10	30	0	114	3	1	162	11	310
Totals	21,235	4	2,438	45	5	2,424	196	26,151
Pct	81.20%	0.02%	9.32%	0.17%	0.02%	9.27%	0.75%	100.00%

	PDL implemented 1/1/11 with only classes with existing clinical criteria enforced (Long Acting Opioids & Singulair™ primarily)
	All remaining physical health PDL PA- enforced beginning 4/13/2010
	PDL updated with changes on 7/1/2010
	42 new PH classes added to the PH PDL with grandfathering of existing patients stabilized on non-preferred products

Table 5 reports the percent of prior authorization requests that were approved. Over 99% of requests are approved and reflects the "provider prevails" requirement of the statute.

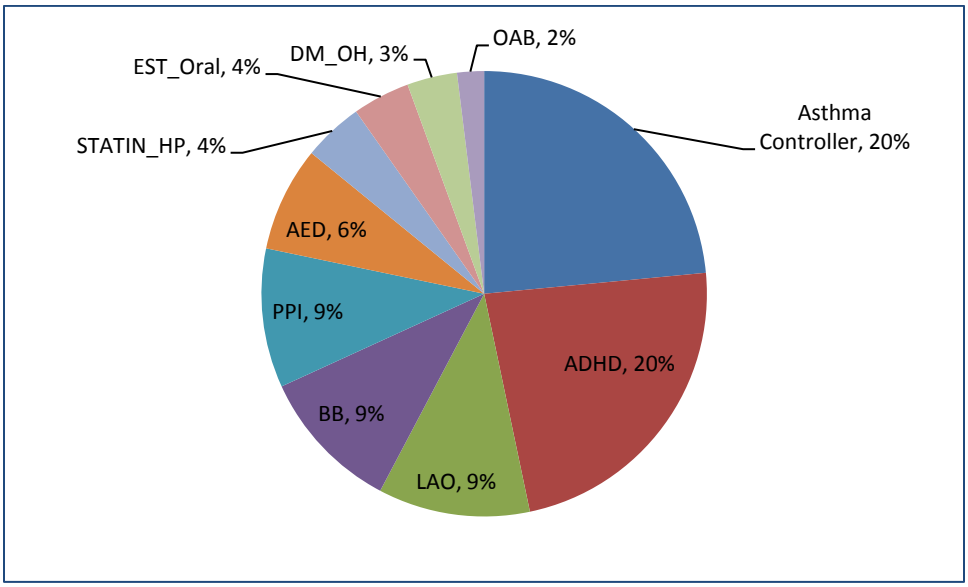
Table 5 - Total Non-Preferred Drug PAs Approved - as Percent of Total Requested

Approved - as Percent of Total Requested								
Month	AUTO PA	ELEC TXN	FAX	ONLINE	PAPER	PHONE	WEB	TOTAL PA's ADJUD.
2010_01	99%	-	100%	100%	-	100%	-	99%
2010_02	100%	-	100%	100%	-	100%	100%	100%
2010_03	100%	-	98%	100%	-	100%	100%	99%
2010_04	100%	-	97%	100%	-	100%	100%	100%
2010_05	100%	100%	99%	100%	-	100%	100%	100%
2010_06	100%	100%	100%	-	-	100%	100%	100%
2010_07	100%	-	98%	-	-	98%	100%	100%
2010_08	100%	-	99%	-	-	100%	100%	100%
2010_09	100%	-	99%	100%	-	99%	100%	99%
2010_10	100%	-	100%	100%	-	99%	100%	100%
2010_11	100%	-	100%	100%	-	97%	100%	99%
2010_12	100%	-	100%	-	-	97%	100%	99%
2011_01	100%	-	100%	100%	100%	99%	100%	100%
2011_02	100%	-	99%	100%	-	100%	100%	100%
2011_03	100%	-	99%	100%	100%	99%	100%	100%
2011_04	100%	-	100%	100%	-	100%	100%	100%
2011_05	100%	100%	100%	100%	-	100%	100%	100%
2011_06	99%	-	100%	-	100%	100%	100%	100%
2011_07	100%	-	100%	100%	-	99%	100%	100%
2011_08	100%	-	100%	100%	100%	99%	100%	100%
2011_09	100%	-	99%	100%	-	99%	92%	100%
2011_10	100%	-	99%	100%	100%	99%	100%	99%
	100%				100%	99%	99%	100%

	PDL implemented 1/1/11 with only classes with existing clinical criteria enforced (Long Acting Opioids & Singulair primarily)
	All remaining physical health PDL PA- enforced beginning 4/13/2010
	PDL updated with changes on 7/1/2010
	>40 new classes added to the PH PDL with grandfathering of existing patients stabilized on non-preferred products

Figure 6 reports the top 10 classes by prior authorization requests made. Notably, 4 of the top 5 classes (Asthma Controllers, ADHD, LAO and PPI) have clinical criteria for appropriate use recommended by the Pharmacy and Therapeutics Committee associated with them.

Figure 6 – Top 10 Classes by PAs Requested (Percent of Total PA requests)



A glossary of acronyms can be found preceding the references.

Table 6 reports the Oregon Pharmacy Call Center statistics for 2010-11. It includes calls for prior authorizations and technical claim processing or trouble-shooting questions. There was a spike in call volume in Q1-2011 when 42 new classes were implemented but this has dropped off subsequently. Notably, 100% of prior authorization requests were processed within 24 hours.

Table 6 – Pharmacy Call Center Statistics

	Q1-2010	Q2-2010	Q3-2010	Q4-2010	Q1-2011	Q2-2011	Q3-2011	Q4-2011
Messages Received	577	218	152	128	333	56	403	217
Total Calls Received	12939	12515	13228	13079	18067	16937	14919	14706
Total Calls on Hold > 5 min	19	6	5	2	15	3	6	3
Abandoned Call Rate	4%	5%	5%	5%	6%	7%	9%	4%
% PA Requests Processed in 24 hrs	100%	100%	100%	100%	100%	100%	100%	100%

Discussion

The PA-enforced PH PDL avoided $3.8 million in pharmacy expenditures and increased supplemental rebate revenues by $0.8 million (total of $4.6 million TF). This exceeds the $4 million budget reduction assigned to HB 2126. It does not include CMS Rebate revenue changes, which cannot be captured due to the ACA changes. The PA-enforced PH PDL preferred drug use rate is at the projected target rate of 90%. Both the "provider prevails" requirement and extensive grandfathering during implementation reduce the potential preferred drug use rate. Other Medicaid programs and managed care plans that use PA

enforcement of their PDLs can achieve 95% preferred rates. Cost avoidance and preferred drug use rate are expected to increase as the program matures under the current policy.

Only $260,000 TF in supplemental rebates were collected for the voluntary MH PDL. This is far short of the $3 million TF assigned to the voluntary MH PDL. Several manufacturers refused to extend supplemental rebates to Oregon in the absence of prior authorization enforcement of non-preferred products despite high voluntary use of preferred drugs. An estimated $2.4 million was unavailable to Oregon during the biennium because of the MH PDL prior authorization exemption. The voluntary MH PDL preferred use rate remains almost flat at 71-72%.

The great majority of prior authorization requests made were automatically generated and approved under the grandfathering policy. Prior authorization requests dropped below 300 per month after the initial grandfathering requirement expired and under 500 after the 2011 PDL expansion. Most prior authorization requests were for Asthma Controller drugs, followed by ADHD drugs. Close to 100% of prior authorization requests are approved, reflecting the "provider prevails" requirement. The few that are denied are done so based upon Pharmacy and Therapeutics Committee recommendations for appropriate use requirements.

Conclusions:

The PA-enforced PH PDL met budget and preferred drug use targets. The Affordable Care Act changes to CMS rebates likely will increase total fund CMS revenues but there may be a reduction in the state revenues.

The voluntary MH PDL is not meeting its budget targets. This is primarily because supplemental rebates were not extended to Oregon by manufacturers in the absence of a prior authorization requirement for non-preferred drugs. Additionally, without the use of prior authorization to inform clinicians and clients of preferred options, market share has not moved to the higher value preferred options.

The statutory requirements of grandfathering, provider prevails, and response to prior authorization requests within 24 hours, were met.

Glossary of Acronyms	
ACA	Affordable Care Act
ADHD	Attention Deficit Hyperactivity Disorder
AED	Antiepileptic Drugs
AIDS	Auto-Immune Deficiency Syndrome
BB	Beta-Blockers
CMS	Center for Medicare and Medicaid Services
DM_OH	Diabetes Mellitus, Oral Hypoglycemic
Est_Oral	Oral Estrogens
FFS	fee-for-service
HIV	Human immunodeficiency virus
LAO	Long-Acting Opioids
MH	Mental Health
OAB	Overactive Bladder
OHA	Oregon Health Authority
OHP	Oregon Health Plan
PA	Prior Authorization
PDL	Preferred Drug List
PH	Physical Health
PMPDP	Practitioner Managed Prescription Drug Plan
PMPM	per member per month
PPI	Proton Pump Inhibitors
SSDC	Sovereign States Drug Consortium
Statin_HP	Statins - High Potency
TF	Total Funds

References

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Appendix A – Current PDL Development Process