State of Washington Joint Legislative Audit & Review Committee (JLARC)



Medicaid Prescription Drug Purchasing: State Preferred Drug List

Report 09-7

September 23, 2009

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Joint Legislative Audit and Review Committee

1300 Quince St SE PO Box 40910 Olympia, WA 98504 (360) 786-5171 (360) 786-5180 Fax www.jlarc.leg.wa.gov

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TABLE OF CONTENTS

Report Summary	1
Part One – Creating and Using the Preferred Drug List and Review of HRSA Compliance	5
Part Two – Information on Medicaid Prescription Drug Usage, Expenditures, and Cost Savings	11
Part Three – PDL Savings Incorporated into Budget	19
Appendix 1 – Scope and Objectives	21
Appendix 2 – Agency Responses	23
Appendix 3 – Preferred Drug List Data	29

Committee Approval

On September 23, 2009, this report was approved for distribution by the Joint Legislative Audit and Review Committee.

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Medicaid Prescription Drug Purchasing: Preferred Drug List

Report 09-7





State of Washington Joint Legislative Audit and Review Committee

> **STUDY TEAM** John Bowden

PROJECT SUPERVISOR Keenan Konopaski

LEGISLATIVE AUDITOR Ruta Fanning

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or contact

Joint Legislative Audit & Review Committee 1300 Quince St SE Olympia, WA 98504-0910 (360) 786-5171 (360) 786-5180 FAX

REPORT SUMMARY

2003 Legislative Directive: Create a Preferred Drug List

In the early 2000s, expenditures for prescription drugs were the fastest growing segment of health care spending. Prescription drug costs were increasing by as much as 17 percent per year. In 2003, the Legislature passed SB 6088 in an attempt to address the escalating state expenditures on prescription drugs. One of the requirements in SB 6088 was the development of a state preferred drug list (PDL).

The Preferred Drug List

The purpose of the preferred drug list is to promote clinically appropriate utilization of pharmaceuticals in a cost-effective manner. Based on cost, safety, efficacy, and effectiveness, drugs are designated as "preferred" or "non-preferred." The practitioner then must: prescribe a preferred drug; allow the pharmacist to substitute a preferred drug for a non-preferred drug; or provide medical reasons for prescribing a non-preferred drug.

Three state agencies are involved in the creation and use of the state preferred drug list. They are the Department of Labor and Industries for the Workers' Compensation Program, the Health Care Authority for administration of the Uniform Medical Plan, and the Health and Recovery Services Administration (HRSA) within the Department of Social and Health Services. HRSA administers the state's Medicaid prescription drug program. This JLARC study focuses on the preferred drug list in relation to HRSA and Medicaid prescription drug expenditures.

The preferred drug list applies to point-of-sale prescription drugs. These are prescriptions filled by retail pharmacies. The list does not apply to drugs provided through managed care programs or by hospitals or clinics.

Additional Prescription Drug Purchasing Requirements

In addition to the directive to create a preferred drug list, SB 6088 required the three state agencies to undertake other activities such as:

- Ensure less expensive generic drugs are substituted for brand name drugs when the quality of care is not diminished;
- Adopt rules governing practitioner endorsement and use of the preferred drug list; and

• Provide for reasonable exceptions to the preferred drug list. To address concerns raised by practitioners as the Legislature considered prescription drug bills, the Legislature allowed certain practitioners the option of signing a prescription with "dispense as written." Such a designation informs the pharmacist that the prescribed drug should be dispensed exactly as written and that the pharmacist may not substitute another drug, for example, a generic drug.

Why a JLARC Review of the Preferred Drug List for Medicaid Prescription Drugs?

The 2003-05 Operating Budget assumed that there would be a \$46.5 million savings in Medicaid payments resulting from the creation and implementation of the preferred drug list. In estimating these potential savings, budget writers assumed that the "dispense as written" provision would be used approximately 30 percent of the time. Budget notes from the following year indicate that this assumption proved to be inaccurate, and the savings were lower than expected. This led to an adjustment in the Medicaid Payments budget, restoring \$9.4 million in the 2004 Supplemental Budget.

Because the projected cost savings and the use of "dispense as written" proved to be different than the original budget assumptions, JLARC members directed staff to review the implementation of the 2003 legislation that directed the creation of the preferred drug list. The Committee requested an analysis of the impact the preferred drug list has had on Medicaid prescription drug expenditures, including a review of the use of the "dispense as written" provision.

Study Results

In presenting the study results, it is important to note that prescription drugs are grouped into different drug classes based on the conditions or diseases that the drugs treat. Some, but not all drug classes contain preferred drugs. The report makes comparisons between drug classes that contain preferred drugs and drug classes that do not, as well as preferred and non-preferred drugs. The report is divided into three parts:

Part One – Creating and Using the Preferred Drug List and HRSA Compliance

SB 6088 directed HRSA, HCA, and L&I to jointly develop a preferred drug list that would ensure the safety, efficacy, and effectiveness of prescription drugs as well as reduce drug costs. The process the three state agencies use to develop the preferred drug list addresses safety, efficacy, effectiveness, and costs, and HRSA fully participates in the process. The process complies with all applicable statutory and regulatory requirements.

Part Two – Information on Medicaid Prescription Drug Usage, Expenditures, and Cost Savings

Six positive indicators suggest that HRSA has achieved savings in Medicaid prescription drug expenditures since the creation of the state preferred drug list. While it is difficult to isolate the exact savings that can be attributed to the state preferred drug list, the positive indicators that suggest savings from the preferred drug list include the following:

- 1. The average daily cost of drugs within the 28 preferred drug classes has increased less than drug inflation and non-PDL drugs (as shown at right);
- Over time, the drug review process has yielded preferred drug designations in the higher use/higher expenditure drug classes;







- HRSA clients are increasingly receiving preferred drugs (as shown at left);
- 4. Use of "dispense as written" on prescriptions has declined;

More Prescriptions are Being Filled with Generic Drugs



HRSA receives supplemental rebates when select brand preferred drugs are dispensed; and

6. The percentage of claims for generic prescription drugs has increased (as shown at right).

Part Three – PDL Savings Incorporated into Budget

For budget development purposes the Legislature may no longer need specific estimates of Medicaid cost savings related to the preferred drug list. HRSA, Office of Financial Management, and legislative fiscal committee staff recognize that the majority of first-time costs savings from adding drugs to the preferred drug list have been realized. Ongoing and additional cost savings from including more drugs on the PDL are now incorporated into the maintenance level budget forecasts. However, it is important for the three agencies to continue to participate in the review process for designating preferred drugs.

Part One – Creating and Using the Preferred Drug List and Review of HRSA Compliance

The Legislature required the development of a state preferred drug list in SB 6088 (2003). This part of the report addresses three aspects of the preferred drug list:

- 1. The process used to select drugs for inclusion on the state preferred drug list;
- 2. Practitioners, pharmacists, and use of the preferred drug list; and
- 3. Compliance with the provisions of SB 6088 by the Health and Recovery Services Administration's (HRSA) within the Department of Social and Health Services.

To facilitate understanding of the review process described below, it is important to note that drugs are grouped into therapeutic drug classes based on the conditions or diseases that the drugs treat. Individual drugs are not singled out, rather classes of drugs are reviewed and drugs from the reviewed classes are selected as preferred. In the remainder of the report, drug classes that contain preferred drugs are referred to as "PDL drug classes." Drug classes that do not contain preferred drugs are referred to as "non-PDL drug classes."

1. The Process for Selecting Preferred Drugs

This JLARC study focuses on the state preferred drug list in relation to HRSA and Medicaid prescription drug expenditures. However, SB 6088 requires three state agencies to jointly create and maintain the state preferred drug list. In addition to HRSA, the other two state agencies are the Department of Labor and Industries for the Workers' Compensation Program and the Health Care Authority for administration of the Uniform Medical Plan. These three agencies participate in a multi-step process that selects drugs for inclusion on the state preferred drug list that have been reviewed for safety, efficacy, and effectiveness and considers potential cost savings.

The process used in selecting preferred drugs begins with HRSA analyzing claims data and making decisions about which drug classes they want submitted for review. HRSA nominates drug classes for review based on potential cost savings. HRSA reports that the drug classes they do not nominate for review are either not expected to produce cost savings or are excluded for clinical reasons. The excluded drug classes usually have one or more of the following characteristics:

- The drugs are necessary to ensure a patient's life (e.g., cancer and HIV/AIDS drugs);
- The prior authorization process provides a valuable medical safety check;
- The drugs are available at the same or nearly the same price (little price difference);
- There is a single brand drug with no competition (sometimes developed for a small population or rare disease);
- There are limited brand drugs with significant therapeutic differences; or
- The drugs have very limited utilization (low volume).

The review process includes 13 other states and Canada at one step and leads to the designation of preferred and non-preferred drugs in Washington and elsewhere. The process involves the following steps as shown in Exhibit 1:

Entity	Entity Actions	
HRSA Staff	Reviews drug utilization data for drug classes with potential Medicaid savings and drug classes to be excluded for medical reasons. Similar analyses are conducted by the other two state agencies that make up the Prescription Drug Program.	Cost
Prescription Drug Program (HRSA, HCA, and L&I)	Nominates drug classes for review that have the greatest potential savings for the state as a whole. Submits nominations to the Drug Effectiveness Review Project.	Cost
Drug Effectiveness Review Project (13 states, Canada, and WA)	Selects drug classes to be reviewed or updated. Produces independent, systematic, evidence- based reviews of the comparative effectiveness and safety of drugs in the drug classes jointly selected by the Drug Effectiveness Review Project members.	Safety, Efficacy, and Effectiveness
Pharmacy and Therapeutic (P&T) Committee	Reviews the evidence-based reports supplied by DERP and makes recommendations to HRSA and the other agencies about drugs for inclusion on the PDL based on safety and effectiveness.	Safety, Efficacy, and Effectiveness
Third-Party Actuary and Prescription Drug Program (HRSA, HCA, and L&I)	Reviews recommendations from P&T and conducts cost analysis to determine which drugs they will recommend to the agency directors as preferred and non-preferred drugs.	Cost, Safety, Efficacy, and Effectiveness
HRSA, HCA, and L&I Directors	Make final decision about which drugs will be included on the preferred drug list.	Cost, Safety, Efficacy, and Effectiveness

Exhibit 1 – Preferred Drug Selection Process
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Prescription Drug Program: a joint effort by DSHS/HRSA, the HCA/Uniform Medical Plan, and the Department of Labor and Industries/Workers' Compensation Program to take necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs, as directed in RCW 70.14.050.

Drug Effectiveness Review Project (DERP): Washington State has joined with 13 other states and Canada in contracting with the Center for Evidence-Based Policy at the Oregon Health and Science University to independently review prescription drugs comparing the safety and effectiveness of drug classes. This joint effort is known as the Drug Effectiveness Review Project (DERP). Each party submits the drug classes they would like reviewed. Submissions are shared with all other parties, and then a joint decision is made regarding which drug classes will be reviewed. Updates are provided annually.

Pharmacy and Therapeutic Committee (P&T): a "technical review committee" established by RCW 70.14.050 to evaluate available evidence regarding the relative safety and effectiveness of prescription drugs in a class and to make recommendations to state agencies regarding the development of a preferred drug list. Members of the P&T Committee also serve as members of the federally required Drug Utilization Review Board. Members of the P&T must have clinical experience prescribing or dispensing covered outpatient drugs or have experience in drug use review, medical quality assurance, or disease state management.

Source: JLARC analysis of HRSA and Prescription Drug Program documents.

2. Practitioners, Pharmacists, and Use of the Preferred Drug List

The purpose of the preferred drug list is to promote clinically appropriate utilization of pharmaceuticals in a cost-effective manner. For this to happen, prescriptions must be filled with preferred drugs. Either the practitioner prescribes a preferred drug or the pharmacist substitutes a preferred drug for a non-preferred drug. A non-preferred drug can be dispensed if the practitioner provides a medical reason. HRSA and the other two state agencies have developed processes and terminology to guide those involved with the writing and dispensing of prescription drugs. This section discusses what it means to be an "endorsing practitioner," the role of the pharmacist related to the preferred drug list, and what "dispense as written" means and how it works.

What are Endorsing Practitioners?

An endorsing practitioner is a health care provider, authorized to prescribe drugs, who has agreed that pharmacies can substitute a preferred drug for a non-preferred drug. Out of the more than 16,000 practitioners who wrote at least one prescription for a Medicaid client in FY 2008, approximately 41 percent (6,600) were endorsing practitioners.

After passage of SB 6088, HRSA and the other two state agencies worked with various key stakeholder groups to develop training materials and hold informational meetings. They mailed packets to approximately 38,000 practitioners about how the initial PDL was created and would be updated, the drugs contained on the initial PDL, an explanation of what it means to be an endorsing practitioner, how to become an endorsing practitioner, and an explanation of how the drug substitution process works.

A practitioner can become an endorsing practitioner by reviewing the PDL and completing a short application form. By endorsing the PDL, the practitioner avoids the time and expense involved in obtaining the prior authorization required before a Medicaid client's non-preferred prescription can be filled. Most prescriptions written by endorsing practitioners are filled without any additional action on the part of the practitioner, patient, or pharmacist.

What is the Role of the Pharmacist Related to the Preferred Drug List?

For both endorsing and non-endorsing practitioners, pharmacists fill prescriptions for preferred drugs without question. When an endorsing practitioner writes a prescription for a non-preferred drug and does not sign "dispense as written," the pharmacist will automatically substitute a preferred drug for the non-preferred drug. The pharmacist can make the substitution without first consulting the practitioner, but must notify the practitioner of the substitution. A non-endorsing practitioner must provide medical justification and obtain prior authorization from HRSA for the non-preferred drug to be dispensed.

What is "Dispense as Written?"

Statute requires that the state agencies provide for reasonable exceptions to the PDL. An endorsing practitioner can sign "dispense as written" (DAW) on a prescription if he or she feels a particular non-preferred drug is in the best interest of the patient. A substitution, such as replacing a more costly brand name drug with a less expensive generic drug, cannot be made without the endorsing practitioner's permission.

A non-endorsing practitioner must receive prior authorization from HRSA for a non-preferred drug prescription to be filled. Exhibit 2 shows how the different scenarios work for endorsing and non-endorsing practitioners for preferred and non-preferred drugs.

Non-Endorsing Endorsing Practitioner Practitioner Writes prescription for: V Writes prescription for: R $\mathbf{R}_{\mathbf{X}}$ Preferred Dru Preferred Drug Pharmacist fills as written Pharmacist fills as written R_x $\mathbf{R}_{\mathbf{X}}$ Non-Preferred Drug Non-Preferred Drug Pharmacist must obtain prior Pharmacist substitutes authorization from HRSA before preferred drug prescription can be filled \mathbf{R} $\mathbf{R}_{\mathbf{X}}$ Non-Preferred Drug Non-Preferred Z Dispense as Written Dispense as Wri Pharmacist must obtain prior authorization from HRSA before Pharmacist fills as written prescription can be filled

Exhibit 2 - Prescription Outcomes for Drug Classes Included in the PDL

Source: JLARC analysis of information supplied by HRSA staff.

3. HRSA Has Complied with PDL Statutory Requirements

As required by statute, HRSA has worked and continues to work with the other two state agencies to develop and maintain the state preferred drug list. Statute requires that the safety, efficacy, and effectiveness of drugs and potential cost savings be considered. The process used by HRSA and the other state agencies to select drugs for inclusion on the PDL conforms with all statutory requirements.

As part of the preferred drug selection process, HRSA encourages and facilitates the substitution of less expensive generic drugs for brand name drugs, and the substitution of less expensive brand drugs for more expensive brand drugs when the quality of care is not diminished.

Lastly, HRSA as required by statute, has adopted rules governing practitioner endorsement and use of the preferred drug list, and has used the dispense as written privilege as the method for granting reasonable exceptions to the PDL.

Part Two – Information on Medicaid Prescription Drug Usage, Expenditures, and Cost Savings

While it is difficult to isolate the exact savings that can be attributed specifically to the creation and use of the preferred drug list, a number of indicators suggest that there have been savings in the Medicaid prescription drug expenditures since the passage of SB 6088 in 2003. This part of the report identifies factors that complicate calculating cost savings and attributing specific cost savings to the preferred drug list. It also elaborates on a set of positive indicators of HRSA prescription drug cost savings.

Context for Understanding the Drug Usage, Expenditure, and Cost Savings Analysis

In analyzing and comparing potential impacts that the state preferred drug list has had on HRSA drug utilization expenditures and potential cost savings, there are three factors that are important to keep in mind:

- 1. By statute, the PDL applies only to point-of-sale, fee-for-service retail pharmacy prescription drug claims and expenditures. Payments or reimbursements for any drugs used as part of managed care or by hospitals and health clinics are excluded.
- 2. The federal Medicare Part D prescription drug program was implemented in 2006. This federal program provides prescription drug coverage to most citizens age 65 years and older. With the implementation of Medicare Part D, there was a significant reduction in HRSA prescription drug claims and expenditures, as HRSA clients who had been receiving both Medicare and Medicaid assistance known as "dual eligible clients" were removed from the Medical Assistance payments budget. For this reason, claims data for the Medicare dual eligible clients in FY 2003 through FY 2006 have been removed from the analysis.
- 3. Since the PDL works to control ingredient costs, or the cost of the drugs themselves, dispensing fees have been removed from the analysis.

After adjusting for these three factors, in FY 2008, there were \$393 million in expenditures that could have been potentially impacted by the creation and use of the state preferred drug list. Approximately \$192 million in expenditures were for prescription drugs in drug classes included on the PDL.

Several Factors Complicate Attributing Specific Cost Savings to the Preferred Drug List

A variety of factors can complicate efforts to determine whether or not a preferred drug list has produced cost savings, and what the specific cost savings might be. In looking at HRSA expenditures after implementing the PDL, there are three areas that can complicate isolating the effects the state PDL has had on expenditures:

1. Additional Cost Containment Efforts Undertaken by HRSA

HRSA has undertaken other cost saving measures in addition to the state PDL. Two cost containment examples are the use of reimbursement mechanisms and efforts to increase the use of generic drugs. First, prior to establishing the PDL, HRSA had already implemented several payment systems to reimburse pharmacies at the lowest of several pricing levels. One such program is the State Maximum Allowable Cost (S-MAC) program. In many cases, the S-MAC program has additional cost impacts for drugs on the preferred drug list. Second, until June 2007, HRSA's contracted pharmacy benefits manager would contact certain practitioners to encourage the use of lower cost generic drugs.

2. Market and Population Factors Affecting Prescription Drug Costs

A number of other factors affect prescription drug prices and are largely beyond the state's control. These factors can cause drug prices to rise or fall and further complicate attributing any changes in expenditures to a single factor such as the creation and use of the preferred drug list. Examples of other factors that affect drug prices include:

- Price Inflation of brand products (exceeding the Consumer Price Index);
- Utilization changes due to population mix and prescribing patterns;
- New, high-cost medications entering the market;
- Advertising and marketing practices;
- Brand drugs going off patent and generics coming onto the market;
- Existing drugs being used to treat conditions beyond their original purpose; and
- The rate and nature of new drugs coming onto the market.

3. Challenges with Methodology for Estimating Cost Savings

To estimate any potential cost savings as a result of implementing a preferred drug list, the actual expenditures for the drugs after creation of the PDL must be subtracted from projections of what expenditures would have been absent the PDL. There are a variety of methods that can be used to calculate projected expenditures, but they all begin to break down a few years after implementing the PDL.

Since the implementation of the state PDL, the Prescription Drug Program has produced estimates of cost savings. In FY 2008, the Prescription Drug Program estimated \$45.5 million in cost savings for HRSA from the use of the state PDL, but acknowledges that other cost avoidance efforts or market forces are also at work. The cost savings estimates are based on drug class utilization trends prior to the drugs being included on the PDL as well as cost trends after implementing the PDL. (Exhibit 10 in Appendix 3 shows the Prescription Drug Program estimated savings from the PDL in FY 2008.)

Positive Indicators of Medicaid Prescription Drug Cost Savings

Despite the difficulty with isolating how the PDL has impacted costs, some indicators show a positive cost savings trend is occurring. This portion of the report analyzes HRSA prescription

drug claims data to see if the creation and use of the preferred drug list has had a positive impact on HRSA drug expenditures and possibly led to cost avoidances or savings. JLARC identifies six areas that indicate savings are occurring with Medicaid prescription drugs. Each indicator examines the potential for cost savings from a different perspective, and for some of the indicators, when appropriate, potential savings estimates are included in the discussion.

1. The Average Daily Cost of Drugs in the 28 Preferred Drug Classes Have Remained Relatively Stable Compared to Inflation and the Non-PDL Drug Classes

Another indicator that the preferred drug list might be contributing to cost savings is to examine the average daily cost of drugs in PDL drug classes and compare them to the average daily costs of non-PDL drug classes and to national drug cost trends. Average daily cost is used because it helps control for changes in total expenditures, numbers of clients, and numbers of claims from year-to-year, and in differences in claims such as number of days supply, doses per day, and prescription strengths.

The average daily cost of drugs within the 28 PDL drug classes has remained relatively stable over the past five years, increasing by only 2.2 percent from FY 2003 to FY 2008. Whereas, the average daily cost of drugs in the non-PDL drug classes have increased by 29.9 percent from FY 2003 to FY 2008. Nationally, drug prices rose by 15.4 percent from FY 2003 to FY 2008. If expenditures for drugs in the PDL drug classes had increased at the national drug inflation rate, HRSA's FY 2008 prescription drug expenditures might have been \$25 million more than they were. Exhibit 3 shows the percentage increases in the average daily costs for PDL and non-PDL drug classes, and the national increase in drug costs over the same time period.





Source: JLARC analysis of HRSA data and U.S. Bureau of Labor national drug inflation statistics.

The average daily costs for 17 of the 28 drug classes were less in FY 2008 than they had been in FY 2003. Seven of the drug classes had increases in their average daily costs, but the increases in three of these drug classes were less than the national drug inflation rate. Four classes were added to the PDL too recently to see a difference. (Exhibit 9, in Appendix 3 shows an example of one of the 17 drug classes where the average daily cost has declined and Exhibit 8 shows an example where the average daily cost has increased.)

If the FY 2003 inflation adjusted average daily cost is applied to each of the 17 drug classes that had decreases in their average daily costs, then expenditures in FY 2008 might have been \$65 million more than they actually were.

2. Over Time, the Drug Review Process Has Yielded Preferred Drug Designations in the Higher Use/Higher Expenditure Drug Classes

Before looking at the analysis, it is important to first understand that prescription drugs are grouped into different therapeutic drug classes based on the conditions or diseases the drugs are designed to treat. HRSA reports that there are 451 therapeutic classes and within these therapeutic classes there are thousands of types of drugs. The state preferred drug list contains 28 drug classes (which combine 49 therapeutic classes) and 165 different preferred drugs with variations in strengths and delivery methods. The 28 PDL drug classes also contain 245 non-preferred drugs also with variations in strengths and delivery methods.

Some of the drug classes that have not been reviewed for possible inclusion of drugs on the PDL still represent significant portions of the HRSA expenditures for prescription drugs, but these drug classes contain drugs where access is often critical for the patient's life (e.g., cancer and HIV/AIDS drugs). Most of the other drug classes not reviewed tend to represent smaller portions of the HRSA drug expenditures. On average, each of the remaining 402 therapeutic drug classes represent about one-tenth of 1 percent of the total HRSA prescription drug expenditures in FY 2008. As shown in Exhibit 4, claims for prescription drug expenditures in FY 2008.





The first seven drug classes on the state PDL were included in April 2004. Seven more classes of drugs were added in the remainder of 2004. Three more drug classes were added in 2005, another seven drug classes were added in 2006, and four more drug classes were included on the PDL in 2007. Each of these classes of drugs is reviewed each year for new studies on the drugs within the class and to evaluate any changes in drugs available within the class. (Exhibit 7 in Appendix 3 shows all of the PDL drug classes, the number of preferred and non-preferred drugs in each drug class, and the number of claims and expenditures in FY 2008.)

While HRSA and the other two state agencies continue to review additional drug classes, the agencies do not expect significant cost savings. In fact, seven drug classes were reviewed by the Drug Effectiveness Review Project and the Washington Pharmacy and Therapeutics Committee, but for safety, efficacy, and effectiveness reasons, no drugs within these drug classes were designated as preferred drugs.

3. HRSA Clients Are Increasingly Receiving Preferred Drugs

Another indicator that the PDL is having positive impacts is to examine the drugs currently contained in the 28 PDL drug classes to see where shifts in the dispensing of preferred drugs have occurred over time. In FY 2008, 87 percent of the drug claims, within the 28 PDL drug classes, were for preferred drugs. In FY 2003, less than half the claims were for drugs that are now

Source: JLARC analysis of HRSA data.

considered preferred. As the use of preferred drugs increases, cost savings are likely to be occurring because preferred drugs tend to be less expensive than non-preferred drugs. Exhibit 5 illustrates the shift to preferred drugs and away from non-preferred drugs.





4. Use of "Dispense as Written" on Prescriptions Has Declined

Since preferred drugs are typically less expensive than the non-preferred drugs, a decrease in the use of "dispense as written" can also be an indicator that cost savings are occurring. According to the 2004 Supplemental Budget notes, in the first year that the preferred drug list was available, endorsing practitioners signed "dispense as written" on about half of all prescriptions for drugs from the seven preferred drug list classes at the time. In FY 2008, endorsing practitioners used DAW for non-preferred drugs on 5.2 percent of all claims.

Some use of DAW is necessary to ensure patients receive the proper medications to most effectively treat their conditions. However, some practitioners have prescribing patterns that show unusually high use of DAW compared to their peers. Engrossed Substitute Senate Bill 5892, which passed in the 2009 Legislative Session, gives HRSA authority to impose limited restrictions on an endorsing practitioner's dispense as written privileges after the HRSA medical director has discussed the data with the practitioner and has allowed sufficient time for the prescribing patterns to be more aligned with other practitioners. Prior to passage of this legislation, HRSA did not believe it had the authority to limit DAW use and had to rely on the voluntary cooperation of practitioners to change their prescribing patterns.

Note: based on current 28 PDL classes. Source: JLARC analysis of HRSA data.

5. HRSA Receives Supplemental Rebates When Preferred Drugs Are Dispensed

One of the advantages of having a preferred drug list is that it helps HRSA obtain supplemental rebates from drug manufacturers. Drug manufacturers already pay rebates to the federal Medicaid program, but agree to pay an additional rebate to the state for each preferred drug that is dispensed.

The amount of supplemental rebates for the Medicaid-only clients has increased each year as more drugs are included on the state PDL and more prescriptions are filled using preferred drugs. Currently, HRSA receives supplemental rebates on 15 of the 28 drug classes. Based on HRSA information regarding supplemental rebates, the state received about \$6.6 million in FY 2008 for drugs dispensed to Medicaid clients. (Exhibit 9 in Appendix 3 identifies the PDL drug classes that generate supplemental rebates.)

6. The Percentage of Claims for Generic Prescription Drugs Has Increased

SB 6088 called for the increased use of lower cost generic drugs. Part of the intent behind the creation of the PDL was to help increase the use of generics by reviewing their safety, efficacy, and effectiveness and selecting them as preferred drugs when possible and when the quality of care is not diminished. The PDL drug classes most likely to generate cost savings are the classes where typically less expensive generic drugs are available for designation as the preferred drugs. (Exhibit 9 in Appendix 3 shows all of the PDL drug classes and the numbers of generic and brand drugs that are designated as preferred and non-preferred drugs.)

Claims for generic prescription drugs have risen from 50 percent of all point-of-sale claims in FY 2003, prior to creation of the PDL, to 65 percent of all point-of-sale claims in FY 2008, as shown in Exhibit 6.



Exhibit 6 – More Prescriptions are Being Filled with Generic Drugs

This increased use of generics indicates that cost savings are likely occurring because the average per claim cost of brand drugs dispensed for Medicaid clients in FY 2008 was 13 times greater than the cost of an average generic claim.

However, it is important to note that HRSA expenditures for brand drugs are greater and increasing faster than expenditures for generic drugs. Brand drug expenditures increased by 44 percent from FY 2003 to FY 2008 (\$239 million to \$344 million) while generic drug expenditures increased by 17 percent in the same time period (\$41 million to \$48 million).

Part Three – PDL Savings Incorporated into Budget

A Specific Savings Estimate May No Longer Be Necessary for Budget Development Purposes

Any changes in Medicaid prescription drug costs attributable to the use of the preferred drug list or to other actions or factors have now been incorporated into the maintenance level budget for HRSA point-of-sale prescription drugs.

For budget development purposes, two forecast workgroups determine what HRSA drug expenditures are expected to be. One group projects the number of HRSA clients that will be filling drug prescriptions. The other group projects the HRSA per-person-per-month cost for prescription drugs. The outputs are multiplied to arrive at projected Medicaid prescription drug expenditures for each month in the coming biennium.

For the first two years following implementation of the preferred drug list, the cost forecast group reported that it looked for specific impacts from implementing the state PDL to include in preparing HRSA expenditure projections. This group found that the incremental changes in drug expenditures as a result of adding new drugs to the PDL were not significant and no longer considers the preferred drug list as a separate factor in its forecast calculations.

The forecast workgroups track and compare actual expenditures with the forecasted expenditures. The workgroups report that overall, the difference between projected and actual monthly drug expenditures averaged less than one-half of 1 percent of the \$393 million in point-of-sale prescription drug expenditures in FY 2008.

While specific estimates of cost savings associated with the preferred drug list may no longer be necessary for legislative budget development purposes, it is important that the three state agencies continue seeking potential cost savings by reviewing drug classes and designating certain drugs as preferred drugs. The process is yielding preferred drug selections that incorporate consideration of drug costs, drug safety, and drug effectiveness.

PERFORMANCE AUDIT OF MEDICAID PRESCRIPTION DRUG PURCHASING

SCOPE AND OBJECTIVES

FEBRUARY 11, 2009



STATE OF WASHINGTON JOINT LEGISLATIVE AUDIT AND REVIEW COMMITTEE

STUDY TEAM

John Bowden

PROJECT SUPERVISOR

Keenan Konopaski

LEGISLATIVE AUDITOR

Ruta Fanning

Joint Legislative Audit & Review Committee 1300 Quince Street SE Olympia WA 98504-0910 (360) 786-5171 (360) 786-5180 Fax Website: www.jlarc.leg.wa.gov

e-mail: neff.barbara@leg.wa.gov

Why a JLARC Performance Audit of Medicaid Prescription Drug Purchasing?

The Joint Legislative Audit and Review Committee (JLARC) included in its 2007-09 Work Plan a performance audit of the Medical Assistance program's use of the state preferred drug list and its impact on the program's prescription drug expenditures.

Background

Creation of the State Preferred Drug List

In 2003, the Legislature passed SB 6088 which, among other requirements, directed the Medical Assistance program within the Department of Social and Health Services, the Health Care Authority, and the Department of Labor and Industries to develop a state preferred drug list (PDL). The purpose of the PDL is to guide practitioners in prescribing medications that have been selected based on clinical evidence of their safety, efficacy, and effectiveness. The legislation directed the agencies to:

- Ensure less expensive generic drugs are substituted for brand name drugs when the quality of care is not diminished;
- Adopt rules governing practitioner endorsement and use of the preferred drug list;
- Prohibit reimbursement for ineffective drugs; and
- Provide for reasonable exceptions to the list.

The Medical Assistance program and the other two agencies have jointly created and implemented the state preferred drug list as required and continue to expand and update the PDL as medications and needs change.

Medical Assistance Prescription Drug Purchases and Costs

JLARC directed staff to focus the performance audit on the Medical Assistance program's use of the preferred drug list. For the Medical Assistance program, the preferred drug list applies to fee-for-service clients who have their prescriptions filled at retail pharmacies also referred to as "point of sale" purchases. In state fiscal year 2007, retail pharmacies filled more than 7.4 million point of sale prescriptions for Medical Assistance program clients – 78 percent of the point of sale prescriptions purchased by all three of the agencies that use the state preferred drug list. The cost to the Medical Assistance program in FY 2007 for these prescription drugs was \$211 million in state dollars and \$195 million in federal dollars – 69 percent of the total payments made by the three agencies for point of sale prescription drugs.

Study Scope

The JLARC performance audit will examine the creation and implementation of the state preferred drug list and the impact the list has had on Medical Assistance prescription drug purchases and costs.

Study Objectives

The performance audit will seek to answer the following questions:

- 1) What is the process for determining which prescription drugs are on the state preferred drug list? How does the state Medical Assistance program participate in this process?
- 2) To what extent do practitioners prescribe drugs which are included on the preferred drug list? How often do practitioners request exceptions to the preferred drug list?
- 3) What efforts does the state Medical Assistance program make to encourage or require practitioners to use the state preferred drug list?
- 4) How has use of the state preferred drug list impacted Medical Assistance prescription drug costs?
- 5) How do actual prescription drug costs compare to historical cost assumptions used to develop the DSHS-Medical Assistance budget?

Timeframe for the Study

Staff will present the preliminary report in May 2009 and the proposed final report in June 2009.

JLARC Staff Contact for the Study

John Bowden

(360) 786-5298

bowden.john@leg.wa.gov



Is funding available to carry out the project?

- Department of Social and Health Services
- Office of Financial Management



STATE OF WASHINGTON DEPARTMENT OF SOCIAL AND HEALTH SERVICES P.O. Box 45010, Olympia, Washington 98504-5010

June 15, 2009

	RECEIVED
	JUN 2 2 2009
Ruta Fanning, Legislative Auditor	~ 4 2003
P.O. Box 40910	JLARC
Olympia, Washington 98504-0910	

Dear Ms. Fanning:

Thank you for your letter dated June 9, 2009 regarding the Joint Legislative Audit and Review Committee's (JLARC) preliminary report on the *Medicaid Prescription Drug Purchasing: Preferred Drug List.* While we realize there are no recommendations in this report on which to respond formally, we would like to comment briefly on the report and our Washington Medicaid Prescription Drug Program.

Our staff has had the privilege of working with John Bowden, JLARC auditor, for this report and we have been impressed with his thorough understanding of all elements of our prescription drug program. We believed from the very beginning of the three-agency Preferred Drug List Program that it was sound in terms of cost savings and providing quality drug therapy to our Medicaid clients. We believed that our association with the Oregon Health Sciences University's Drug Effectiveness Project has allowed us to provide vital, evidence-based information to our prescribers to guide them in selecting appropriate cost-effective drug therapy. This JLARC report details the successes of our program, both clinically and financially. While working with Mr. Bowden, we thought we were providing him with all the intricate details of our pharmacy program, and it turns out that the report revealed much more than any one of us actually knew at the time.

I thank you and your staff for the opportunity to work with you to produce this very important report. The Department finds this report to be a credible resource that accurately describes our Preferred Drug List Program.

I would like to recommend that MaryAnne Lindeblad attend your June 17 and July 22 meetings when this report is presented to the Committee. Please feel free to contact her at (360)725-1786 or by email at <u>lindem@dshs.wa.gov</u> to complete the meeting arrangements and if you have any questions.

Sincerely,

Susan N. Dreyfus Secretary



STATE OF WASHINGTON OFFICE OF FINANCIAL MANAGEMENT

Insurance Building, PO Box 43113 • Olympia, Washington 98504-3113 • (360) 902-0555

June 30, 2009

TO: Ruta Fanning, Legislative Auditor Joint Legislative Audit and Review Committee

FROM:

Victor A. Moore Director

SUBJECT: REVIEW OF JLARC PRELIMINARY REPORT – MEDICAID PRESCRIPTION DRUG PURCHASING: STATE PREFERRED DRUG LIST

Thank you for the opportunity to comment on this Joint Legislative Audit and Review Committee (JLARC) preliminary report. Review of this subject is very timely, given the difficult fiscal situation facing the state.

As you requested, my operating budget staff have reviewed this report. We appreciate the positive findings in your report that the preferred drug list (PDL) was implemented within all statutory and regulatory requirements, that many positive indicators suggest that the PDL has saved state resources, and that ongoing calculations of PDL impact cannot be disaggregated from current trends for budget development purposes. The findings also provide us with much needed feedback on our efforts to control health care expenditures.

and the

We look forward to participating further with you and your staff on this important issue.

cc: Carole Holland, Senior Budget Assistant, OFM Nick Lutes, Budget Assistant, OFM Jonathan Seib, Senior Policy Advisor



APPENDIX 3 – PREFERRED DRUG LIST DATA

The proton pump inhibitor drug class is one of the 17 drug classes that shows a decrease in average daily cost. Proton pump inhibitors are a group of drugs whose main action is to provide long-lasting reduction of gastric acid production. One-third of the drugs in the proton pump inhibitor drug class have been designated as preferred drugs. In FY 2008, HRSA spent \$16.4 million on proton pump inhibitors. If the average daily cost for proton pump inhibitors in FY 2003 (\$3.75) had been the average daily cost in FY 2008, the total HRSA expenditures for proton pump inhibitors would have been approximately \$23.7 million. Exhibit 7 shows the changes in average daily costs for the proton pump inhibitor drug class.





Source: JLARC analysis of HRSA data.

There are seven drug classes where the average daily cost continued to increase even after preferred drugs were designated. In some of these drug classes, this may have occurred because a high percentage of the drugs within the drug class were designated as preferred drugs to meet patient needs and/or safe and effective generic drugs were not available. Inhaled corticosteroid is one drug class where the selection of preferred drugs did not affect the average daily cost. Inhaled corticosteroids are drugs used for the long-term control of asthma. HRSA spent \$3.8 million on inhaled corticosteroids in FY 2008. The point at which drugs were designated as preferred drugs within the drug class are preferred drugs. More importantly perhaps is the fact that none of the available drugs in this drug class are generics. Exhibit 8 shows that the average daily cost continues to increase because less expensive drugs within the drug class are not available to be routinely dispensed.





Source: JLARC analysis of HRSA data.

Name of PDL Drug Class	Date Drugs Were Included on the PDL	# of Preferred Drugs in Drug Class (generic/brand)	# of Non- Preferred Drugs in Drug Class (generic/brand)	Total # of Claims in FY 2008	Total Ingredient Expenditures in FY 2008
Ace Inhibitors	4/1/2004	5/0	4/11	162,788	\$ 544,800
ADHD Drugs*	4/1/2006	8/7	1/10	138,196	\$ 13,522,043
Alzheimer Drugs*	10/1/2005	1/2	0/4	5,796	\$ 883,811
Antidepressants (2 nd Gen.)	7/1/2005	7/1	4/12	395,772	\$ 16,602,815
Antiemetics	7/1/2006	1/0	1/6	5,338	\$ 1,108,470
Antiplatelets*	4/1/2006	0/2	1/1	97,551	\$ 2,337,914
Atypical Antipsychotics*	10/1/2006	2/12	0/2	268,473	\$ 82,503,033
Beta Agonists*(Inhaled)	4/1/2007	3/6	0/8	78,344	\$ 1,908,113
Beta Blockers	6/1/2004	10/0	2/15	154,976	\$ 1,211,445
Calcium Channel Blockers	6/1/2004	6/0	2/16	76,071	\$ 1,588,864
Estrogens	12/1/2004	2/6	1/25	33,978	\$ 712,009
Hepatitis C Drugs*	10/1/2007	0/1	0/1	2,079	\$ 3,476,776
Inhaled Corticosteroids*	7/1/2005	0/8	0/1	32,876	\$ 3,816,045
Immune Agents for MS*	10/1/2008	1/5	0/1	2,740	\$4,805,405
Long Acting Opioids	5/1/2004	2/0	4/9	104,762	\$ 9,244,119
Macrolides	1/1/2007	6/1	0/10	59,391	\$ 949,856
Nasal Corticosteroids*	10/1/2006	2/1	0/8	52,354	\$ 3,548,554
New Antihistamines	4/1/2004	4/0	0/5	100,065	\$ 827,642
NSAIDS/Cox-II Inhibitors	7/1/2004	20/0	0/23	189,979	\$ 2,030,954
Oral Hypoglycemics	4/1/2004	4/0	3/9	45,615	\$ 272,982
Overactive Bladder*	9/1/2004	2/2	1/8	26,481	\$ 1,062,876
Proton Pump Inhibitors*	4/1/2004	3/5	0/4	218,431	\$ 16,372,700
Sedative Hypnotics	10/1/2007	1/0	1/3	38,694	\$ 504,942
Skeletal Muscle Relaxants	9/1/2004	4/0	4/10	123,839	\$ 841,068
Statins*	4/1/2004	3/1	0/5	155,796	\$ 7,607,645
Target Immune Modulators*	7/1/2006	0/3	0/5	3,968	\$ 6,047,730
Thiazolidinediones*	10/1/2006	0/2	0/0	22,173	\$ 3,319,712
Triptans*	4/1/2004	0/3	0/4	18,747	\$ 3,212,720
Totals		97/68	29/216	267,072	\$186,678,849

Exhibit 9 - Preferred Drug List Data

*Indicates HRSA receives supplemental rebates for these drug classes. However, the expenditures column is not net of any supplemental rebates received.

Source: JLARC analysis of HRSA data.



Exhibit 10 – Prescription Drug Program Estimated HRSA Savings from Each of 26 PDL Drug Classes in FY 2008

Note: Hepatitis C drugs and Immune Agents for MS are missing due to their recent addition to the PDL.

Source: JLARC analysis of Prescription Drug Program data.