

STATE AUDITOR'S OFFICE PERFORMANCE AUDIT

Department of Labor & Industries Prescription Drugs

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BRIAN SONNTAG
STATE AUDITOR

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EXECUTIVE SUMMARY

Why we did this audit

Washington state pays about \$800 million annually for prescription drugs for injured workers, Medicaid patients, prison inmates, public employees and others.

Injured workers are eligible for financial help and medical care — including prescription drugs — through the Department of Labor & Industries' (L&I) Workers' Compensation program. Those benefits are funded by premiums paid by employers and workers to the state's Industrial Insurance Fund.

L&I processed more than 400,000 prescription drug claims in 2009 at a cost of nearly \$29 million. A primary goal of the program is to hold down prescription drug costs by paying for the most effective and least expensive medications to treat injured workers' conditions.

We audited L&I prescription drug purchases in fiscal year 2009 to answer the following questions:

Does the L&I Workers' Compensation program pay a reasonable and appropriate amount for prescription drugs?

- If costs appear too high, what actions could contain costs without compromising quality care, and what would be their likely effects?
- If costs appear reasonable, does the Department have additional opportunities to contain costs without compromising quality care? What would be the likely effects if these options were pursued?

State lawmakers have directed L&I and other state agencies that purchase prescription drugs, primarily the Health Care Authority and the Department of Social and Health Services, to use specific strategies to hold down costs. These generally fall into three categories: (1) purchase generic instead of brand-name drugs whenever their use does not compromise patient health and safety; (2) set rates as low as possible for all drugs; and (3) limit the amount of drugs dispensed. Health-care providers and researchers have identified effective tactics — which we describe in this audit as “leading practices” — to accomplish those objectives.

Audit results

L&I purchases prescription drugs for injured workers through reimbursements to pharmacists. It has attained a relatively high generic drug use rate, and has limited the amount of drugs it dispensed to injured workers. The Department is using many leading practices to contain drug costs, but has also missed significant savings opportunities by not regularly updating its drug pricing schedule. Specifically, we found that:

- **During fiscal year 2009**, generic drugs represented nearly 88 percent of all prescription drugs purchased. Brand-name drugs were provided for the other 12 percent, mostly when generic equivalents weren't available. These percentages compare favorably with other states and other Washington state agencies. Industry sources indicate that generic drugs often cost 65 percent less than brand names.

- **Until fiscal year 2011, L&I had not updated** its reimbursement rates for years — partly because of concerns pharmacists would no longer participate in the program — and was paying more than other state agencies for the same drugs. Although L&I compared favorably to other states' workers compensation programs, it could have saved more than \$7.1 million in 2009 and a similar amount in 2010.
- **L&I currently pays a more reasonable amount** for prescriptions than it did in the past, but its rates are still not as low as HCA's. L&I could save an additional \$1.5 million to \$2.3 million per year if it adopted a rate it had previously considered or HCA's 2011 price structure.
- **The agency could save more money** if it allowed permanently disabled workers to use mail-order pharmacies for long-term prescription refills and if it encouraged pill-splitting. Had those practices been used in 2009, we estimate mail-order pharmacies would have reduced L&I's costs by up to \$107,000 and pill-splitting by up to \$117,000, in addition to savings related to updating the reimbursement rates.
- **State law prevents L&I** from adopting two other cost-saving practices that would further reduce costs. First, through a provision known as a "carve-out," pharmacists are prohibited from dispensing therapeutically equivalent generics for certain classes of drugs if the physician has prescribed a brand-name drug. Second, the law allows physicians to write "dispense-as-written" prescriptions that promote brand-name drugs and limit generic use. We estimate removing these two restrictions would save a combined total of at least \$146,000 per year based on 2009 spending patterns.

The table on the next page summarizes what L&I could have potentially saved in fiscal years 2009 and 2010 if our recommended strategies had been in place, and what the Department would save each year in the future if it adopts them for fiscal year 2012 and beyond.

Summary of potential savings in 2009-10 and future years			
Cost-reduction strategy	Could have saved in 2009	Could have saved in 2010	Estimated future annual savings
Reduce reimbursement rates to level previously considered by L&I or set by the Health Care Authority. ¹	\$7.1 million to \$8 million	\$6.6 million to \$7.4 million	\$1.5 million to \$2.3 million ²
Use mail-order pharmacies for L&I claimants on permanent disability.	\$107,000	\$107,000	\$107,000
Encourage pill-splitting when physicians deem it safe.	\$117,000	\$117,000	\$90,000
Restrict “dispense-as-written” and carve-out prescriptions for brand-name drugs when equivalent generics are available.	\$146,000	\$146,000	\$146,000
Prevent pharmacists from dispensing brand-name drugs if physician has prescribed generics. (Implemented for FY 2011)	\$31,000	\$31,000	N/A
Total	\$7.5 million to \$8.4 million	\$7 million to \$7.8 million	\$1.8 million to \$2.6 million
Notes: ¹ Estimates for 2010 and future years have been adjusted to reflect a 3.6-percent reduction in the average wholesale price paid for prescription drugs that took effect in September 2009. ² The upper end may be more difficult to obtain than the lower end of the range.			

Recommendations

The Legislature and L&I should take several actions to further contain prescription drug costs in the Workers’ Compensation program by increasing the use of generic drugs, reducing reimbursement rates for all drugs, and adopting additional leading practices.

Update reimbursement rates annually

1. To ensure L&I does not pay more than it needs to for prescription drugs, we recommend that for fiscal year 2012, the Department reduce its prices for generic and brand-name drugs with a goal of matching those rates paid by HCA. L&I should reexamine its pricing annually by benchmarking its rates to those paid by the HCA, DSHS or other public and private prescription drug purchasers.

Increase the use of generics

2. We recommend the Legislature revise state law (RCW 69.41.190) to permit physicians to prescribe brand-name drugs only when generic therapeutic equivalents are not available. To accomplish this, lawmakers should modify the carve-out provision so it no longer exempts certain drug classes from the generic requirement, and should modify the “dispense-as-written” provision so it no longer prohibits pharmacists from substituting less expensive, therapeutically equivalent generics. If the law were changed, physicians who thought a brand-name drug was needed still could obtain prior approval from L&I to prescribe that drug. This recommendation would not result in therapeutic interchange (requiring physicians to prescribe drugs with different active ingredients).

Use other leading practices to hold down costs

We recommend L&I adopt several leading practices to maximize cost-savings in the prescription drug program. Specifically, the Department should:

3. Amend the Washington Administrative Code to allow low-cost mail-order pharmacies to provide 90-day prescriptions for permanently disabled workers who require ongoing prescriptions. The Department should also explore financial incentives as a way to move the prescriptions for permanently disabled workers to mail-order pharmacies.
4. Encourage pill-splitting when physicians think it is safe and economical to do so. L&I should communicate this information through its website, bulletins and preferred drug list.
5. Exercise its contractual audit authority to verify that its private benefits manager is collecting and remitting all rebates owed and that its fees do not exceed the amounts allowed by contract. L&I may want to partner with HCA and the benefit manager's other government customers to reduce the cost of verification.

What's next?

All audits of state agencies and programs are reviewed by the Joint Legislative Audit and Review Committee (JLARC). They are also reviewed by other legislative committees whose members wish to consider findings and recommendations on specific topics.

Representatives of the State Auditor's Office will review this audit with JLARC's Initiative 900 Subcommittee in Olympia. The public will be given the opportunity to comment at this hearing.

The Legislature and L&I will determine whether to accept the audit recommendations. The State Auditor's Office conducts periodic follow-up evaluations to assess the status of recommendations and may conduct follow-up audits at its discretion.

INTRODUCTION

Audit Overview

When a worker is injured on the job in Washington, he or she is eligible to receive financial help and medical care — including prescription drugs—from the Department of Labor & Industries' (L&I) Workers' Compensation program. Those benefits are funded through employer and worker premiums paid into Washington State's Industrial Insurance Fund.

L&I processed more than 400,000 prescription drug claims in 2009 at a cost of nearly \$29 million. One of the goals of the program is to hold down prescription drug costs by paying for the most effective and least expensive medications to treat injured workers' conditions.

We conducted this audit to determine:

Does the L&I Workers' Compensation program pay a reasonable and appropriate amount for prescription drugs?

- If costs appear too high, what actions could contain costs without compromising quality care, and what would be their likely effects?
- If costs appear reasonable, does the Department have additional opportunities to contain costs without compromising quality care? What would be the likely effects if these options were pursued?

Audit scope and methodology

We audited L&I's Workers' Compensation program, focusing on prescription drug practices and payments for fiscal year 2009. We reviewed some prescription drug information from earlier and more recent years when issues were identified.

To determine whether L&I's prescription drug costs are reasonable, we evaluated whether the agency was following leading practices to help contain drug costs without compromising the quality of care for injured workers. We identified those leading practices from public, private, consumer-oriented and non-profit sources, as well as from other performance audits on this topic in other states.

To assess whether L&I paid a reasonable and appropriate amount for prescription drugs during fiscal year 2009, we obtained benchmarks that measure the success of a workers' compensation program in a number of areas towards containing prescription drug costs. We obtained these benchmarks from public, private and non-profit sources and cite them throughout the report. These benchmarks included other state workers' compensation programs, private benefits managers who administer public and private workers' compensation programs, and other Washington state agencies that pay for prescription drugs.

In determining the extent to which L&I paid for brand-name drugs when therapeutic generic equivalents were available, we tested the accuracy, completeness and classification of L&I's prescription drug data.

We conducted this audit under the authority of state law (RCW 43.09.470), approved as Initiative 900 by Washington voters in 2005, and in accordance with generally accepted government auditing standards prescribed by the U.S. Government Accountability Office. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes the provisions of Initiative 900 and how the audit addressed the law's specific requirements.

Appendix B describes our audit methodology in more detail.

L&I is just one of several state agencies that pay for prescription drugs as part of the services they offer. Other agencies with significant prescription drug expenditures include the Health Care Authority (state workers), and the departments of Social and Health Services (Medicaid clients), Health (immunizations), Corrections (criminal offenders) and Veterans Affairs (veterans). **Appendix E** shows annual drug expenditures for these and other state agencies. The issues and recommendations in this audit may also help other state prescription drug programs.

BACKGROUND

The Department of Labor & Industries (L&I) was established in 1911 to provide industrial insurance to workers and employers in Washington. The Workers' Compensation program, funded with premiums paid by employers and workers, provides injured workers with financial help and medical care. In fiscal year 2009, L&I spent about \$600 million on medical costs for injured workers, including prescription drugs.

In fiscal year 2009, L&I paid about \$29 million for more than 400,000 individual prescriptions for injured workers, which accounted for about 5 percent of the program's medical spending. Administrative costs represent approximately \$500,000 — about 2 percent — of the agency's total prescription drug expenses. Prescription drug costs are influenced by several factors, including the type and amount of drugs prescribed, the number of prescriptions and the price the program pays for those drugs.

Exhibit 1 shows drug costs and claim information from fiscal years 2004 through 2009.

Exhibit 1					
L&I Pharmacy Claims and Payments					
Fiscal Year	Payments to Pharmacies for Prescriptions (\$ in millions)	Claims with Payments to Pharmacies	Average Cost Per Claim	Number of Prescriptions	Average Cost Per Prescription
2004	\$27.7	53,700	\$515	430,700	\$64
2005	\$26.9	54,700	\$493	424,100	\$64
2006	\$26.1	54,100	\$483	417,900	\$63
2007	\$26.9	53,300	\$505	414,600	\$65
2008	\$28.0	54,900	\$511	407,900	\$69
2009	\$28.6	57,800	\$495	404,700	\$71
Source: Department of Labor & Industries.					
Note: Totals reflect the dates prescriptions were filled. We did not audit this data. Totals in 2009 for payments to pharmacies and the number of prescriptions differ from those elsewhere in this report because the other sections reflect the dates claims were paid.					

Most work-related claims involve injuries or pain management, and can include lost work time. As a result, the most common prescription drugs purchased by L&I fall into the following categories:

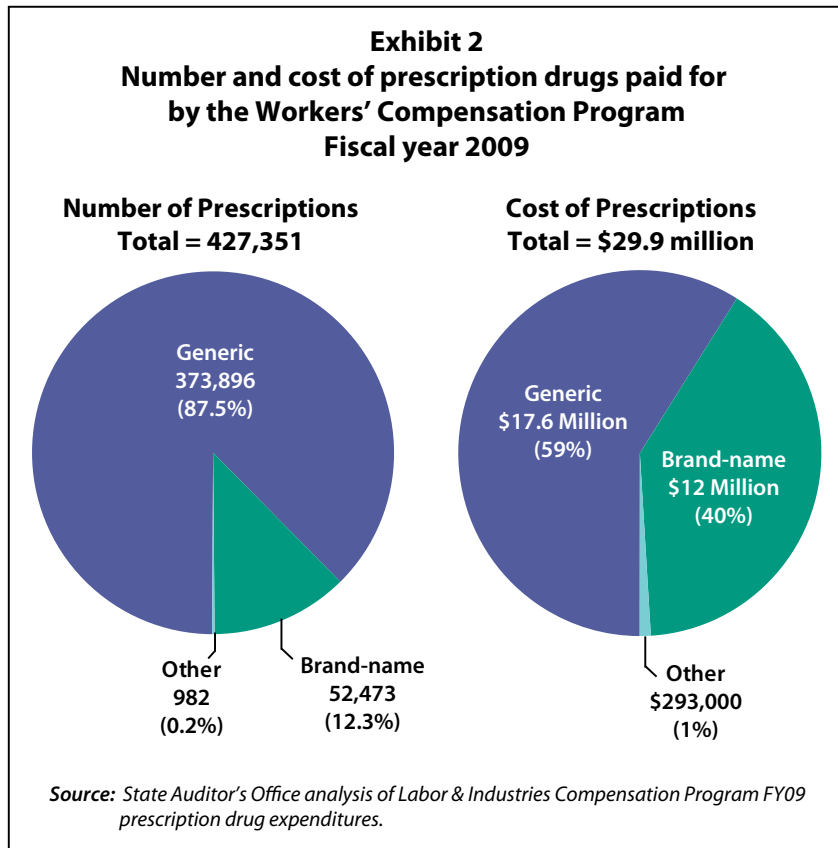
- Narcotics and other pain management drugs (25 percent)
- Anti-convulsants (15 percent)
- Non-steroidal anti-inflammatory drugs (9 percent)
- Anti-depressants (8 percent)
- Skeletal muscle relaxants (7 percent)

A more complete list of commonly prescribed drugs is in **Appendix F**.

Many brand-name prescription drugs have generic equivalents. The Federal Drug Administration (FDA) uses scientific evidence to determine which generic drugs have the same active ingredients and can be expected to perform essentially the same as a brand-name drug. Those drugs are called "therapeutic equivalents." For example, the FDA allows Meloxicam, a generic equivalent, to be substituted for the brand-name Mobic to treat arthritis pain.

Exhibit 2 shows that brand-name drugs accounted for only 12 percent of the total number of prescriptions in 2009, but represented 40 percent of the cost of those prescriptions.

Although drug manufacturers often provide rebates and discounts for brand-name drugs, generic drugs still generally cost much less. According to recent reports by the FDA and other organizations, generics typically cost 65 percent less than brand-name drugs.



AUDIT RESULTS

Summary

This performance audit addressed the following questions:

Does the L&I Workers' Compensation program pay a reasonable and appropriate amount for prescription drugs?

- If costs appear too high, what actions could contain costs without compromising quality care, and what would be their likely effects?
- If costs appear reasonable, does the Department have additional opportunities to contain costs without compromising quality care? What would be the likely effects if these options were pursued?

Overall, we found L&I was using most leading practices for controlling prescription drug prices, which contributed to the high rate of prescriptions for generic drugs in the Workers' Compensation program. In 2009, generics represented nearly 88 percent of all prescription drugs purchased for injured workers. When a therapeutically equivalent generic was available, the utilization rate was 99 percent. Those percentages compare favorably to those of other states and Washington state agencies.

However, L&I could have saved significant amounts if it had regularly updated its prescription drug prices, as shown in **Exhibit 3**. L&I's average prices in 2009 were higher than those paid by the Health Care Authority for state workers or by DSHS for Medicaid clients.

We also found L&I was not using other leading practices, including encouraging pill-splitting and allowing the use of mail-order pharmacies for its pension claimants. We estimate these two practices could save up to an additional \$90,000 and \$107,000 per year, respectively.

Exhibit 3			
Summary of potential savings in 2009-10 and future years			
Cost-reduction strategy	Could have saved in 2009	Could have saved in 2010	Estimated future annual savings
Reduce reimbursement rates to level previously considered by L&I or set by the Health Care Authority. ¹	\$7.1 million to \$8 million	\$6.6 million to \$7.4 million	\$1.5 million to \$2.3 million ²
Use mail-order pharmacies for L&I claimants on permanent disability.	\$107,000	\$107,000	\$107,000
Encourage pill-splitting when physicians deem it safe.	\$117,000	\$117,000	\$90,000
Restrict "dispense-as-written" and carve-out prescriptions for brand-name drugs when equivalent generics are available.	\$146,000	\$146,000	\$146,000
Prevent pharmacists from dispensing brand-name drugs if physician has prescribed generics. (Implemented for FY11)	\$31,000	\$31,000	N/A
Total	\$7.5 million to \$8.4 million	\$7 million to \$7.8 million	\$1.8 million to \$2.6 million
Notes: ¹ Estimates for 2010 and future years have been adjusted to reflect a 3.6-percent reduction in the average wholesale price paid for prescription drugs that took effect in September 2009.			
² The upper end may be more difficult to obtain than the lower end of the range.			

Issue: State law requires and L&I is using several leading practices to control prescription drug expenses.

Health-care providers and researchers have identified strategies to hold down the cost of prescription drugs. We identified leading practices for this audit by reviewing public, private, consumer-oriented and non-profit sources, including the federal Food and Drug Administration, the Generic Pharmaceutical Association, the National Academy for State Health Policy and the Health Policies Studies Division of the National Governors Association Center for Best Practices.

We also identified leading practices from other performance audits that examined this topic, including those issued by the U.S. Government Accountability Office, the Inspector General for the Department of Health and Human Services, and the states of California, Colorado, Idaho, Kansas, Connecticut, Kentucky, Missouri, New Jersey, New York and North Carolina. Additional detail about our audit methods appears in **Appendix B**.

Some of the most commonly used practices we identified include requiring the use of generic prescription drugs and establishing preferred drug lists. We also identified other practices that we believe could significantly reduce costs, could be put in place relatively easily, and that are widely considered effective by insurers and providers.

Practices designed to control the price paid for drugs:

1. Requiring or encouraging the use of generic drugs.
2. Establishing a preferred drug list.
3. Requiring prior authorization for dispensing non-preferred drugs.
4. Excluding certain drugs and clearly communicating which drugs are not covered.
5. Negotiating rebates with drug manufacturers.
6. Paying higher dispensing fees for generic drugs to encourage generic substitution.
7. Requiring pharmacists (not physicians) to fill prescriptions at pre-established prices.
8. Reducing the use of "dispense-as-written" orders to use brand-name drugs when generics or other preferred drugs are available.
9. Regularly reviewing and updating drug pricing for pharmacies to ensure pricing is as low as possible.
10. Encouraging pill-splitting to lower prescription costs when physicians think it is safe to do so.
11. Using mail-order pharmacies.

Practices primarily designed to limit the amount of drug used:

12. Limiting the number of days supplied per prescription.

13. Conducting system-based drug utilization reviews.

L&I has implemented or adopted all of the practices except Nos. 8-11.

Labor & Industries has implemented several leading practices for the Workers' Compensation prescription drug program. For example:

- A. State law requires the use of therapeutically equivalent generic drugs and a preferred drug list (PDL). L&I uses both practices, which has contributed to the program's high generic and preferred drug utilization rates.
- B. L&I is using several other practices designed primarily to control the price paid for prescription drugs.
- C. L&I is using practices designed primarily to control the amount of prescription drugs used.

- A. State law requires the use of therapeutically equivalent generic drugs and a preferred drug list (PDL).** State law (RCW 70.14.050) requires the program to use generic prescription drugs rather than brand-name drugs when the quality of care is not diminished. Accordingly, L&I has adopted rules requiring generic substitution for brand-name drugs unless the physician indicates a brand-name drug should be "dispensed as written."

With few exceptions — discussed later — L&I paid for brand-name drugs only when therapeutically equivalent generics were not available. In fiscal year 2009, nearly 88 percent of all prescription drugs it paid for were generics, and brand-name drugs accounted for just over 12 percent. Many of those brand-name drugs did not have a generic therapeutic equivalent. However, when a therapeutically equivalent generic drug was available, the program's generic prescription rate was 99 percent. Industry sources indicate generic drugs often cost 65 percent less than brand names.

The law also requires L&I and other state health-care agencies to use an evidence-based preferred drug list (PDL) to control drug costs. To select drugs for the PDL, the state Pharmacy and Therapeutics Committee relies on research by the Oregon Health & Science University. Committee members are appointed by officials from L&I, HCA and DSHS, and include four doctors, four pharmacists, one physician's assistant and one nurse practitioner. The Committee evaluates drugs found to be safe and effective and makes recommendations to L&I, HCA and DSHS. The three agencies review the cost of the recommended drugs and select those to add to the PDL. The process is designed to ensure the committee selects only safe, effective and relatively low-cost drugs for the PDL.

Physicians are required to prescribe from the PDL unless they participate in the state's Therapeutic Interchange Program or obtain prior authorization from L&I. Doctors who register as "endorsing" physicians agree to allow pharmacists to substitute a preferred drug for the non-preferred drug they have prescribed **unless** they sign the prescription pad as "dispense as written." In exchange, those physicians do not have to get L&I's prior approval to prescribe a non-preferred drug. About 7,200 of the 40,000 registered physicians in Washington are "endorsing." They prescribed 64 percent of L&I's fiscal year 2009 Workers' Compensation prescriptions.

Exhibit 4 shows that L&I's generic use rates compare favorably to those of other state health-care programs and to those in other state workers' compensation programs. In addition, the national Workers' Compensation Research Institute found that in 16 states during 2005 and 2006, the average generic prescription rate was 85 percent.

B. L&I has adopted other practices to hold down prescription costs. L&I uses several other practices designed primarily to control the price paid for prescription drugs. For example, the Department:

- **Requires prior authorization for physicians** to prescribe drugs that are not on the preferred drug list (PDL). "Non-endorsing" physicians who want to prescribe a different drug than the one on the PDL must first request prior authorization from L&I. In addition, before obtaining this authorization the claimant must have first tried the preferred drug and received no benefit.
- **Excludes certain drugs from the PDL** and clearly communicates which drugs are not covered. L&I does not include on its PDL any prescription drugs that would not be appropriate for the types of injuries workers may have. For example, drugs intended for pediatric use are not included. The PDL includes some drugs, such as Lipitor, that are not typically prescribed for injured workers, but L&I will not pay for them without prior authorization. L&I communicates this information to providers through its website and the PDL.
- **Negotiates rebates with drug manufacturers** for brand-name drugs. L&I uses a private benefits manager (PBM) to negotiate drug rebates from drug manufacturers. In fiscal year 2009, L&I received nearly \$100,000 in net rebates from brand-name drug manufacturers after paying the benefits manager its 50 percent commission.

Exhibit 4	
Generic Utilization Rates in Washington and Other States	
Program/State	Generic Utilization Rate
Washington state public health care programs	
L&I — workers' compensation	88%
HCA — state employees	78%
DSHS — Medicaid clients	73%
Other states' workers' compensation programs	
Oregon	80%
Ohio	74%
North Dakota	73%
Florida	54%
Sources: State Auditor's Office analysis of L&I prescription drug expenditures. Self-reported information from other agencies and states.	
Notes: Rates reflect the most recent data available from 2008 or 2009. Differences in the types of injuries or illnesses can affect the types of drugs prescribed and generic utilization rates.	

- **Pays pharmacies more to fill generic prescriptions** than brand-name. L&I pays pharmacists \$4.50 to dispense a generic prescription and \$3 for a brand-name prescription. This is an incentive for pharmacists to dispense generics when physicians authorize a generic substitution. We reviewed dispensing fees for nine other states and found that L&I was one of only four that pay a higher fee for generic prescriptions. Washington also pays lower dispensing fees than most of those states, shown in **Exhibit 5**.
- **Requires drugs to be filled by pharmacists** (not physicians). Washington physicians may dispense drugs to patients, but L&I will not reimburse these drugs, only an office visit fee. L&I's fee schedule clearly states it will not pay for drugs that are directly dispensed. A 2010 study by the Worker's Compensation Research Institute found that when physicians filled prescriptions in Florida, they typically did so at costs that were 35 percent to 60 percent higher than pharmacists.

C. Controlling the amount of drugs used. L&I uses two leading practices to limit the volume of drugs prescribed:

- Limiting the number of days supplied per prescription to reduce the likelihood that more drugs are dispensed than needed to treat an injury, particularly for initial prescriptions that may not be effective or may have unwanted side effects. L&I administrative rules (WAC 296-20-03011 (1)) prohibit pharmacies from filling more than a 30-day supply. In December 2009, L&I reported to the Legislature that from July 2008 through March 2009, its "first-fill prescriptions" averaged nine days of medication.
- Using a point-of-sale system to monitor prescription that ensures:
 - Quantities do not exceed a 30-day supply.
 - Refills are not provided too soon.
 - Doses are not excessive or unsafe.
 - Prescriptions are for preferred drugs, unless exemptions apply.

Exhibit 5 L&I Dispensing Fees Compared to Workers' Compensation Programs in Other States			
State	Generic Drugs	Brand-Name Drugs	Incentive Fee for Generic Drugs
Alabama	\$10.40	\$8.00	\$2.40
Nevada	\$8.58	\$8.58	—
California	\$7.50	\$4.00	\$3.50
Michigan	\$5.50	\$3.50	\$2.00
Tennessee	\$5.10	\$5.10	—
Kentucky	\$5.00	\$5.00	—
Washington	\$4.50	\$3.00	\$1.50
Colorado	\$4.00	\$4.00	—
Minnesota	\$3.65	\$3.65	—
Vermont	\$3.15	\$3.15	—
Source: Published data or staff reports from the listed states' workers compensation programs. Similar data was not available from other states.			

Issue: L&I could have saved \$7.1 million in 2009 by updating its prescription drug prices. It has not followed other practices that could further reduce costs.

Although L&I uses several leading practices to hold down prescription drug costs, we found it was not using others that could significantly reduce expenses. For example, the Department:

- A. Had not updated its drug pricing for years, and as a result paid higher drug prices in fiscal year 2009 than other state agencies.
- B. Did not verify that the private benefits manager paid L&I all the rebates it is owed.
- C. Did not use mail-order pharmacies to help contain costs.
- D. Did not encourage pill-splitting for reducing prescription drug costs when physicians thought it was safe to do so.

A. L&I had not updated its drug reimbursement pricing for years, resulting in it paying higher prices than other state agencies. Currently, administrators at L&I, HCA and DSHS set the drug reimbursement rates separately for their programs. A typical practice is to reimburse pharmacists for a drug's average wholesale price (AWP), minus a certain percentage. Once the agencies set their prices, pharmacies sign agreements to use the updated fee schedules.

When we audited this program, L&I had last updated its pricing in 1996. Between then and fiscal year 2010, L&I's reimbursement rate was AWP minus 10 percent. L&I's pricing was comparable to or better than that of 10 other state workers' compensation programs we reviewed. However, we found L&I had not updated its rates or compared them to those of other Washington state agencies. As a result, it paid much higher prices than did HCA and DSHS, especially for generics, as shown in **Exhibit 7**.

Exhibit 7			
State agency prescription rates, fiscal year 2009			
Agency	Generic drug price	Brand-name price	Years in place
L&I	AWP ¹ minus 10%	AWP minus 10%	14 years
HCA ²	AWP minus 67%	AWP minus 16%	2 years
DSHS	AWP minus 50%	AWP minus 14%	10 years
Source: Published data and interviews with agency staff.			
Notes: ¹ AWP is average wholesale price. The table does not reflect HCA mail-order pharmacy prices. ² HCA pricing changed to AWP less 66% and AWP less 13% in September 2009. This change was made in response to a 3.6% decrease in AWP pricing. DSHS made similar changes to its pricing.			

Exhibit 8 shows that if L&I had paid the same rates as HCA or other rates it previously considered, L&I would have spent between \$7.1 million and \$8 million less in 2009 than it did.

L&I officials said they had not lowered prices since 1996 because they were concerned some pharmacists would refuse to fill prescriptions for Workers' Compensation clients. Before 2007, pharmacists who filled an injured worker's first prescription before the claim was approved risked not being reimbursed if the claim was denied. State law changed in April 2007 to allow pharmacies to be reimbursed automatically for the first fill of an injured worker's prescription.

L&I officials agreed this statutory change reduced the likelihood that pharmacists would quit doing business with L&I if it lowered its drug pricing. They acknowledged that many pharmacies were likely to accept lower L&I rates if they already had agreed to lower pricing for the HCA and DSHS Medicaid programs. However, L&I indicated it also has to balance lower pricing with workers' continued access to pharmacies.

In April 2010, L&I analyzed how low it could reduce its generic drug prices. The analysis considered two options: AWP minus 50 percent, or AWP minus 60 percent, which the analysis identified as "the industry standard." However L&I rejected AWP minus 60 percent for fear that some pharmacies might not accept fees that were so close to those paid by Medicaid.

L&I subsequently reduced its fiscal year 2011 reimbursement rate for generics from AWP minus 10 percent to AWP minus 50 percent — the same rate as DSHS. Although one pharmacy stopped doing business with L&I, the price reduction will save L&I nearly \$5 million per year based on 2009 prescription patterns. However, L&I did not adjust its 2011 rate for brand-name drugs, which remains higher than HCA and DSHS rates. We estimate L&I could save an additional \$2.3 million per year if it matched HCA's rates of AWP minus 66 percent for generics and AWP minus 13 percent for brand-name drugs. If L&I matched HCA's brand name pricing but priced generics at AWP less 60 percent, combined brand and generic savings would total \$1.5 million.

Exhibit 8 Impact on fiscal year 2009 drug costs resulting from L&I's use of rates that exceed HCA's rates			
	Generic drug price	Brand-name price	Total prescription drugs
Total spent in FY09	\$17.6 million	\$12 million	\$29.6 million
Estimated savings if L&I had paid HCA rate	\$7.4 million	\$640,000	\$8 million
Estimated savings if L&I matched a lower generic rate (AWP minus 60 percent) it previously considered	\$6.5 million	No Change	\$7.1 million
Source: State Auditor's Office analysis of L&I's Workers' Compensation program FY09 prescription drug expenditures.			

Because of a recent lawsuit, average wholesale pricing information will not be available after September 2011, so Washington and other states will have to use other benchmarks to set their drug prices. The vendor that produces AWP information intends to offer an alternative product, and other price-setting tools may emerge. The vendor, First Data Bank, has not revealed the alternative, but possibilities include the average price used by Medicare or the maximum allowable cost, which is based on surveys of actual pharmacy costs.

- B. L&I does not verify that it receives all appropriate rebates from its private benefits manager.** As noted earlier, L&I uses a private benefits manager to negotiate rebates with drug manufacturers for brand-name drugs. Drug manufacturers then remit the rebates they owe to the private benefits manager, which retains 50 percent and remits the remainder to L&I. The Department has contractual authority to audit the manager's activities but has not verified that it received the correct rebate amounts.
- C. L&I does not use mail-order pharmacies to help reduce prescription drug costs.** Leading practices for controlling the costs related to recurring and ongoing prescription drug use include the use of mail-order pharmacies and 90-day fills. This practice is convenient and is especially applicable for claimants who are on permanent disability, who have a stable need for certain prescription drugs over the long-term. During fiscal year 2009, L&I paid \$3.6 million for about 25,000 prescriptions for nearly 900 pension claimants who have permanent disabilities. If all L&I claimants had used mail-order pharmacies for all of their non-opioid prescriptions, L&I would have spent \$269,000 less in drug costs and dispensing fees. However, industry literature suggests that even when they use financial incentives, other public and private drug programs have been able to shift no more than 40 percent of their prescriptions voluntarily to mail-order. Incentives include requiring claimants to pay some or all of the difference between mail-order prices and higher retail prices, or providing claimants with a one-time incentive payment. If L&I could shift 40 percent of its prescriptions for pension claimants to mail-order, we estimate it could save approximately \$107,000 per year.
- D. L&I does not encourage pill-splitting to hold down prescription drug costs.** Some health care organizations hold down drug costs by prescribing pills with twice the needed dose and having the patient split them into halves when it is safe to do so. For example, Group Health uses pill-splitting, and its website indicates the savings range from 23 percent to 50 percent. L&I already allows pill-splitting — it paid for 570 prescriptions during fiscal year 2009 for which physicians had instructed patients to split pills — but it does not actively encourage the practice.

Important clinical and patient safety factors must be considered when pursuing pill-splitting as a way to save on prescription drug costs. For example, patients must be able to split the pills easily and accurately to ensure doses do not vary by more than 15 percent from the target level.

Pill-splitting is not unanimously supported in the health-care industry, but researchers have concluded that many drugs are safe to split, subject to consultation between patients and their physicians. This research is discussed in the Consumer Reports article we summarized in **Appendix D**.

In fiscal year 2009, L&I paid for about 8,200 prescriptions for 1,700 claimants involving types of drugs that Consumer Reports indicated were safe to split. The total cost of those drugs was \$732,000. If these prescriptions had been for twice the dose and split, L&I could have saved up to \$234,000. However, if L&I encouraged physicians to write prescriptions that instruct patients to split pills when they thought it was safe to do so, there is no way to know how often this would occur. If physicians had decided to do this for 50 percent of the 2009 prescriptions that were identified as safe to split, L&I would have saved \$117,000. Using L&I's lower 2011 drug pricing, potential savings total nearly \$90,000. Pill-splitting to save money is suitable only when physicians determine their patients can split pills safely and accurately.

Issue: L&I has a high generic drug utilization rate, but changes in the law could further improve that rate.

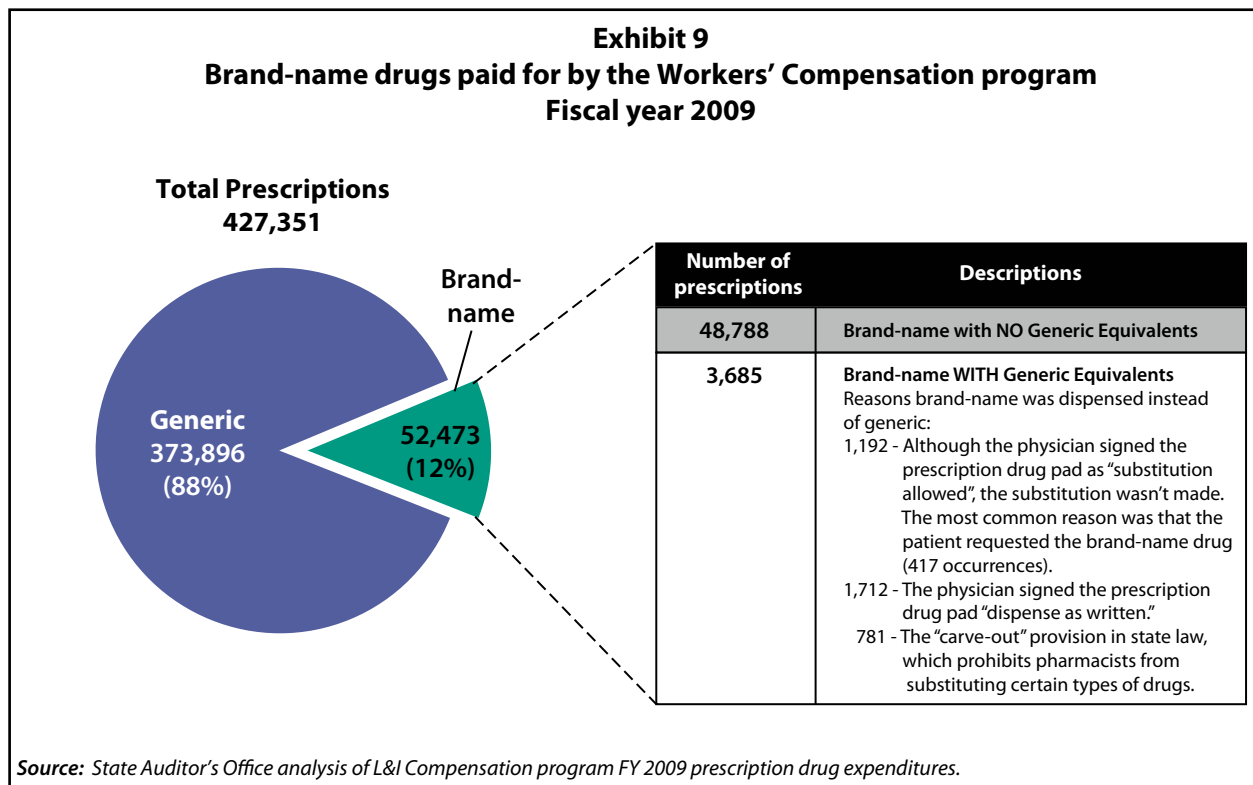
Only about 52,000 of the 427,000 prescriptions L&I paid for in fiscal year 2009 (12 percent) were for brand-name drugs. However, as shown in **Exhibit 9**, a generic therapeutic equivalent was available for only about 3,700 of these 52,000 prescriptions, or less than 1 percent of total prescriptions.

These 3,700 prescriptions included instances in which:

- The pharmacist had not substituted a generic for a brand-name drug when authorized to do so.
- Under what is known as a carve-out provision in state law, the pharmacist was prohibited from substituting certain drugs on the PDL list for non-preferred drugs.
- The physician required that the pharmacist dispense the brand-name drug prescribed using a dispense-as-written order.

Although it was rare for brand-name drugs to be dispensed when generic equivalents were available, we think L&I could largely eliminate those instances by:

- **Denying payments to pharmacists for brand-names** when the physician had authorized a generic substitution. For fiscal year 2009, we found 1,192 instances where L&I paid for brand-name drugs when therapeutic equivalents **were** available and the physician had authorized a generic substitution. Those instances cost the program \$30,000 to \$60,000 more than generics would have cost. In November 2010, after we pointed out this issue, program officials changed the point-of-sale system to deny these types of prescriptions.



- **Removing provisions that prohibit pharmacists from dispensing therapeutically equivalent drugs** for brand-name drugs. Currently, such prohibitions occur in two situations:
 - State law (RCW 69.41.190) does not allow pharmacists to substitute generics for brand-name drugs for refills of certain types of prescriptions, including anti-psychotics, anti-depressants and chemotherapy drugs. This statutory provision is known as a carve-out.
 - When doctors who register as endorsing providers write dispense-as-written prescriptions for brand-name drugs, pharmacists are not allowed to substitute generic equivalents.

Industry and regulatory sources suggest that carve-out and dispense-as-written prescriptions add costs with no measurable benefits. The Food and Drug Administration has continuously asserted that generic therapeutic equivalents have the same clinical effects as their brand-name counterparts for all drug classes, including those listed under Washington state's carve-out provisions. In an April 16, 1997, letter to the National Association of the Board of Pharmacy, the FDA stated the same position it maintains today:

"...FDA's position on drug substitution is...if one therapeutically equivalent drug is substituted for another, the physician, pharmacist, and patient have FDA's assurance that the physician should see the same clinical results and safety profile. Any differences that could exist should be no greater than one would expect if one lot of the ...[brand-name drug] was substituted for another."

In addition, a 2008 study sponsored by the Pharmaceutical Care Management Association found that carve-out provisions substantially increase prescription drug costs with no clinical benefit to consumers.

If generic therapeutic equivalents had been dispensed instead of carve-out and dispense-as-written prescriptions of brand-name drugs, L&I could have saved \$146,000 to \$215,000 in 2009 alone. Restricting these carve-out and dispense-as-written provisions would require legislative action. If the law were changed, physicians who thought a brand-name drug was needed still could obtain prior approval from L&I to prescribe that drug. Program officials said they thought such requests would result in an initial increase in workload that would likely taper over time.

This legislative change could reduce costs in the Workers' Compensation program as well as those administered by HCA and DSHS, whose prescription drug programs are collectively 20 times larger than L&I's, as shown in **Appendix E**.

RECOMMENDATIONS

The Legislature and L&I should take several actions to further contain prescription drug costs in the Workers' Compensation program by increasing the use of generic drugs, reducing reimbursement rates for all drugs, and adopting additional leading practices.

Update reimbursement rates annually

1. To ensure L&I does not pay more than it needs to for prescription drugs, we recommend that for fiscal year 2012, the Department reduce its prices for generic and brand-name drugs with a goal of matching those rates paid by HCA. L&I should reexamine its pricing annually by benchmarking its rates to those paid by the HCA, DSHS or other public and private prescription drug purchasers.

Increase the use of generics

2. We recommend the Legislature revise state law (RCW 69.41.190) to permit physicians to prescribe brand-name drugs only when generic therapeutic equivalents are not available. To accomplish this, lawmakers should modify the carve-out provision so it no longer exempts certain drug classes from the generic requirement, and should modify the "dispense-as-written" provision so it no longer prohibits pharmacists from substituting less expensive, therapeutically equivalent generics. If the law were changed, physicians who thought a brand-name drug was needed still could obtain prior approval from L&I to prescribe that drug. This recommendation would not result in therapeutic interchange (requiring physicians to prescribe drugs with different active ingredients).

Use other leading practices to hold down costs

We recommend L&I adopt several leading practices to maximize cost-savings in the prescription drug program. Specifically, the Department should:

3. Amend the Washington Administrative Code to allow low-cost mail-order pharmacies to provide 90-day prescriptions for permanently disabled workers who require ongoing prescriptions. The Department should also explore financial incentives as a way to move the prescriptions for permanently disabled workers to mail-order pharmacies.
4. Encourage pill-splitting when physicians think it is safe and economical to do so. L&I should communicate this information through its website, bulletins and preferred drug list.
5. Exercise its contractual audit authority to verify that its private benefits manager is collecting and remitting all rebates owed and that its fees do not exceed the amounts allowed by contract. L&I may want to partner with HCA and the benefit manager's other government customers to reduce the cost of verification.

AGENCIES' RESPONSES



STATE OF WASHINGTON

April 7, 2011

The Honorable Brian Sonntag
Washington State Auditor
P.O. Box 40021
Olympia, WA 98504-0021

Dear Auditor Sonntag:

Thank you for this opportunity to formally respond to the Performance Audit on Prescription Drugs relating to the Department of Labor & Industries' (L&I). Like Governor Gregoire, we support the use of performance audits as an important tool to improve state government, which is why we worked closely and extensively for nearly a year with the Auditor's staff on this audit.

L&I is the seventh largest workers' compensation insurer in the nation, covering 2.3 million workers and 161,000 employers. It pays out \$1.2 billion each year in medical expenses and partial replacement of lost wages for workers who suffer job-related injuries or illnesses.

As part of this function, the department strives to improve injured workers' access to appropriate and quality care while driving down the costs of prescription drugs. These efforts have had the following results:

- L&I has saved millions through its industry-leading, high use rate of generic drugs. Its rate of 88 percent, compared with 54 to 80 percent for other states' workers' compensation programs, generated around \$7.25 million in savings in Fiscal Year 2009. To our disappointment, these savings are not noted in this audit.
- Likewise, although the audit does not include a direct comparison of drug prices for workers' compensation programs, L&I's pharmacy reimbursement rate is lower than the rate in 43 other states.
- The independent Workers' Compensation Research Institute (WCRI) recently identified L&I as having one of the lowest cost prescription drug programs among 17 other states it studied. WCRI will publish its research report in the next few months.
- The gap between drug prices paid by L&I and the Health Care Authority (HCA), which was emphasized in the audit report, has largely been addressed by 2010 changes in L&I's pharmacy fee schedule.

The Honorable Brian Sonntag
April 7, 2011
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We are concerned that the audit repeatedly benchmarks L&I to the HCA. Unfortunately, this comparison has limited application because L&I has a different line of business with additional billing workload and risks that make it less attractive to pharmacies. It is also an apples-to-oranges comparison because, unlike L&I, HCA is able to use patient co-payments and deductibles as incentives for choosing lower cost drugs. In addition, the Auditor's estimated cost savings are based on debatable assumptions, and in some cases, depend on legislative policy changes. Therefore, we believe the savings stated in the audit are not attainable.

While we disagree with several conclusions in the audit report, we appreciate the cooperative and respectful interactions between the Auditor's Office and L&I staff in completing this audit. We have enclosed a joint response and will report on our progress on completing these action items.

Sincerely,



Judy Schurke, Director
Department of Labor & Industries



Marty Brown, Director
Office of Financial Management

Enclosure

cc: Jay Manning, Chief of Staff, Governor's Office
Jill Satran, Deputy Chief of Staff, Governor's Office
Wendy Korthuis-Smith, Director, Accountability & Performance, Governor's Office
Kimberly Cregeur, Governor's Liaison on Performance Audits, Accountability & Performance, Governor's Office

Official Response to the Performance Audit on Prescription Drugs
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April 7, 2011

Employees of the Department of Labor & Industries (L&I) and the Office of Financial Management (OFM) have provided a coordinated response for each issue and corresponding recommendation. In addition to the audited agency, OFM jointly responds to performance audits to provide perspective on potential statewide or multi-agency issues, including policy, strategic planning, performance management, budget, accounting, purchasing, human resources, information technology, labor relations, and risk management. We prepared this document in response to the final draft audit report delivered on March 17, 2011.

Issue 1: State law requires, and L&I is using, several leading practices to control prescription drug expenses.

L&I RESPONSE: Washington is the only state that has established therapeutic interchange using an evidence-based state Preferred Drug List. This leading practice requires pharmacists in most cases to substitute a preferred drug alternative when a physician has written a prescription for a non-preferred drug in the same drug class.

As a result of L&I policies and extensive work with other state agencies, L&I has an extremely high rate of use of generic medications. Workers' compensation programs in other states fill prescriptions as generics at a rate of 54 to 80 percent, for an average generic use rate of 70 percent. L&I, meanwhile, fills 88 percent of all prescriptions paid for by the agency with less-expensive generics. Compared to the average for these other states, we estimate that L&I's emphasis on generics saves about \$7.25 million per year.

In addition, among drugs that have a generic equivalent (same active ingredient), L&I's use of generics is 99 percent. A study by the Workers' Compensation Research Institute (*Prescription Benchmarks Study for Michigan, 2010*) found much lower – and costlier – figures for other states. The median for the 16 states studied was an 83 percent use of generics for medications for which generic products were available.

Action Steps and Timeframe:

- L&I will continue to participate in interagency activities to implement leading practices pursuant to laws on prescription drug purchasing for state programs. (*corresponds to Recommendation #1*)

OFM RESPONSE: Washington State has prescription drug purchasing laws for state health care programs that make our state a national leader in innovative practices for controlling prescription costs. For example, L&I, along with the state's Health Care Authority (HCA) and the Medicaid Purchasing Administration, has been a key participant in developing and maintaining the state Preferred Drug List and rules around therapeutic interchange. Their work has resulted in substantial pharmacy savings to the state.

Issue 2: By updating its prescription drug prices, L&I could have saved \$7.1 million in Fiscal Year 2009. It has not followed other practices that could further reduce costs.

L&I RESPONSE: L&I is already using appropriate benchmarks to review program performance and adjust fees based on market rates. Last year, we contracted with the

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Workers' Compensation Research Institute (WCRI) – an independent, nationally recognized research organization – for a benchmarking study to compare L&I's prescription drug costs and use with those of workers' compensation programs in 17 other states. WCRI's preliminary results indicate that, for the most commonly prescribed medications, L&I drug prices were below the median for the other states. Because of L&I's extremely high use of generics, our overall average price per pill for all medications was about 35 percent below the 17-state median. The study did not include L&I's July 2010 reduction in pharmacy fees, which further reduced drug prices.

After the period examined in both the audit and the WCRI study, L&I reduced pharmacy fees in its July 2010 fee schedule update. This is an annual process to review and adjust L&I fee schedules for all provider types. The July 2010 adjustments in pharmacy fees have already closed most of the gap between drug prices paid by L&I and HCA. The remaining gap between L&I and HCA rates equates to about \$1.5 million per year (based on FY 2009 utilization levels) – much less than the \$7.1 million cited by SAO for FY 2009.

We do not agree with the audit conclusion that the HCA drug prices are the most appropriate benchmark for our program. The audit does not consider the significant differences between workers' compensation coverage and other types of health insurance. From the pharmacies' perspective, workers' compensation patients present additional workload and much higher risks. When filling a prescription, the pharmacist needs to determine not only that the patient has an approved L&I claim, but that the particular medication is related to treating the patient's work-related injury. Otherwise, L&I will recoup payments from pharmacies if the bill is retroactively denied. Pharmacies do not have these additional tasks and financial risks for other types of health insurance, so they would be less likely to give L&I the same deep discounts that they accept from HCA or other employee health plans.

We need to find the balance between holding down prescription costs and maintaining access to pharmacies for injured workers statewide. Driving reimbursements too far down could actually drive overall costs up. If small rural pharmacies leave the program due to low reimbursements, savings from lower pharmacy fees could be cancelled out by higher wage-replacement costs because it would likely take injured workers longer to find a pharmacy to fill their prescriptions. We will continue to use appropriate benchmarks to adjust our fee schedule based on changes in market rates. However, it may be unrealistic for L&I to achieve savings by further reducing fees.

Action Steps and Timeframe:

- After the WCRI study is completed in September 2011, L&I will use the results and comparisons with drug prices paid by other health care payers — including workers' compensation programs in other states — to review and adjust our reimbursement levels, if appropriate. We will determine the feasibility of further reducing prescription reimbursement rates as part of our annual provider fee schedule update. (July 2012)

OFM RESPONSE: We are concerned that the audit repeatedly benchmarks L&I to the Health Care Authority (HCA). Although it is tempting to believe that state agencies should or could use the same rates for prescription drugs, this comparison has limited application. L&I has a

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fundamentally different line of business with additional billing workload and risks that make it less attractive to pharmacies. It is an apples-to-oranges comparison because, unlike L&I, HCA is able to use patient co-payments and deductibles as incentives for choosing lower-cost drugs.

The audit appears to disregard how L&I's pharmacy fees compare to fees in workers' compensation programs in other states. For example, L&I's pharmacy fee schedule is lower (as a percentage of Average Wholesale Price) than the pharmacy fee schedules used by 43 other states.

Recommendation 3: Mail order pharmacies.

L&I RESPONSE: Offering financial incentives to encourage injured workers to switch from retail pharmacies to mail order conflicts with our mandate to cover all costs for proper and necessary treatment for injured workers. This change would require statutory authorization. The convenience of receiving a 90-day supply of medication via mail order could prove to be an incentive for some L&I patients. However, offering this option is not likely to save \$107,000 per year as suggested, since the uptake would be lower than that of other programs with financial incentives.

Action Steps and Timeframe:

- Evaluate and determine if mail order could be offered to some pension claims. (January 2012)

OFM RESPONSE: Currently, Washington Administrative Code (WAC) 296-20-03011 limits prescriptions to a 30-day supply, so increasing to a 90-day supply would require rulemaking to amend the WAC. However, under Executive Order 10-06, all non-critical rule development and adoption are currently suspended through December 31, 2011.

Recommendation 4: Pill splitting.

L&I RESPONSE: We disagree with this recommendation. This is a controversial strategy that is opposed by multiple regulatory and professional organizations including the U.S. Food and Drug Administration (FDA), American Medical Association, American Pharmacists Association, and the National Association of Boards of Pharmacy. This is a patient safety issue. Concerns include patient confusion about correct dosages; patients' ability to accurately split the tablet; questionable content uniformity of split tablets; the difficulty of splitting some tablets; and the fact that not all drugs are safe to split.

In addition to patient safety concerns, potential savings to L&I are low for the following reasons:

- Our programs rarely use the more expensive brand name drugs that are typical candidates for pill-splitting initiatives.
- Many medications that physicians are more likely to recommend for pill splitting (i.e., medications to control high blood pressure and high cholesterol) are not routinely covered by workers' compensation.
- Our potential financial liability increases greatly for errors associated with inaccurate pill splitting or other problems caused by injured workers not taking medications correctly.

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OFM RESPONSE: We also disagree with this recommendation. In addition, the HCA Public Employee Benefits Board) and Medicaid Purchasing Administration share the concerns expressed by L&I. Any potential savings would likely be outweighed by the cost of implementation and medication errors associated with adverse consequences due to inaccurate splitting.

Recommendation 5: Contractual audits.

L&I RESPONSE: L&I will work with the HCA and other contracting agencies to develop a strategy for auditing the pharmacy benefits management (PBM) contractor that will include a coordinated effort involving all participating agencies. This strategy will take into account industry standards and individual agency needs for audits of similar programs. It will allow the department to establish a regular, ongoing audit protocol that is cost-effective and consistent among all participating entities.

Action Steps and Timeframe:

- Collaborate with HCA and other agencies to develop a cost-effective and ongoing audit plan that is consistent among all agencies. (January 2012)

OFM RESPONSE: We would encourage use of this type of audit only if the potential savings exceed the cost of the annual audit. Since this type of specialty audit is expensive and L&I receives less than \$100,000 per year in rebates, any efforts to audit should necessarily be done in collaboration with the other contracting agencies.

Issue 3: L&I has a very high generic drug utilization rate, but changes in the law could further improve that rate.

L&I RESPONSE: Changes in the law would have minimal impact because, among those medications with generic equivalents, 99 percent of prescriptions paid for by L&I are filled as generics. For all types of medications combined, L&I's generic use rate is 88 percent. In contrast, generic use rates for workers' compensation programs in other states range from 54 to 80 percent. As noted under Issue #1, this difference between L&I and the average for other workers' compensation programs generated about \$7.25 million savings in FY 2009.

OFM RESPONSE: Changes in the law would have a much larger impact on other state agency programs, insurers, and health care providers than on L&I. These other payers have much higher use of brand name drugs and greater opportunities for generic savings. The changes would also increase the agencies' administrative costs for handling requests for exceptions.

According to the HCA and Medicaid Purchasing Administration, the current "carve out" provisions and generic substitution laws already allow for generic substitution of preferred brand drugs when a generic is available.

Recommendation 2, associated with this issue, is directed at the Legislature and does not require our response.

APPENDIX A: INITIATIVE 900

Initiative 900, approved by Washington voters in 2005 and enacted into state law in 2006, authorized the State Auditor's Office to conduct independent, comprehensive performance audits of state and local governments.

Specifically, the law directs the Auditor's Office to "review and analyze the economy, efficiency, and effectiveness of the policies, management, fiscal affairs, and operations of state and local governments, agencies, programs, and accounts." Performance audits are to be conducted according to U.S. General Accountability Office government auditing standards.

In addition, the law identifies nine elements that are to be considered within the scope of each performance audit. The State Auditor's Office evaluates the relevance of all nine elements to each audit. The table below indicates which elements are addressed in the Prescription Drug audit. Specific issues are discussed in detail in the Audit Results and Recommendations sections of this report.

I-900 Element	Addressed in audit
1. Identification of cost savings	Yes. The audit identifies several actions L&I can take to save \$1.8 million per year.
2. Identification of services that can be reduced or eliminated	No. As long as the state continues to serve as the insurance provider for injured workers, it must continue to offer prescription drug coverage.
3. Identification of programs or services that can be transferred to the private sector	No. The audit identifies additional ways L&I could contain prescription drug costs, but none would require privatization of L&I services.
4. Analysis of gaps or overlaps in programs or services and recommendations to correct them	No. The audit identifies cost-cutting opportunities. We did not identify gaps or overlaps in service to injured workers.
5. Feasibility of pooling information technology systems within the department	No. The IT function for the prescription drug program already resides within L&I's Workers' Compensation program.
6. Analysis of roles and functions of the department, and recommendations to change or eliminate departmental roles or functions	Yes. We recommend several operational changes and improvements at L&I.
7. Recommendation for statutory or regulatory changes that may be necessary for the department to properly carry out its functions	Yes. The audit recommends changes in state law and agency regulations that would increase the use of generic drugs and hold down drug costs.
8. Analysis of departmental performance data, performance measures, and self-assessment systems	Yes. We determined the Department's measures of preferred drug utilization and prescription drug spending permit well-informed decision-making.
9. Identification of best practices	Yes. The audit identifies many leading practices for containing prescription drug costs. L&I has implemented most, but not all of them.

APPENDIX B: METHODOLOGY

To gain an understanding of the L&I's Workers' Compensation program and how it contains its prescription drug costs, we:

- Reviewed prior audits of the program to identify potential risks and to obtain an understanding of the program and the requirements that apply to it.
- Interviewed legislative staff, program management, pharmaceutical manufacturers and other state agency officials.

To determine how we would assess the program's practices for containing prescription drug costs, and how effective they were at containing drug costs, we:

- Researched leading practices for containing prescription drug costs. We identified leading practices from public, private, consumer-oriented and non-profit sources. We also identified leading practices from other performance audits that examined this same topic for other states.
- Obtained benchmarks that measure the success of a workers' compensation program in a number of areas towards containing prescription drug costs. We obtained these benchmarks from public, private and non-profit sources. These benchmarks included other state workers' compensation programs, private benefits managers who administer public and private workers' compensation programs and other Washington state agencies that pay for prescription drugs.

To determine whether L&I had implemented leading practices to contain prescription drug costs, and to assess how effective those practices were or the impacts where those practices were not in place, we:

- Analyzed business processes and practices to contain the cost of prescription drugs. Part of this work included examining L&I's information systems and how well they supported the containment of prescription drug costs.
- Compared L&I's processes and practices to leading practices, state laws and L&I policies, as required. Where departures from leading practices, laws or policies were observed, we performed tests to assess the impact from those departures. Where L&I asserted best practices were in place, we affirmed they were in place.
- Tested statistical, random and risk-based selections of payments to pharmacies looking for instances where L&I was overcharged for prescriptions. These tests focused on quantities, prices, number of days supplied, and the amount paid by L&I.
- Tested the accuracy, completeness and classification of L&I's prescription drug data, which we used in this audit. We confirmed selected drug data with the pharmacies that submitted the prescription claims for payments. We also reviewed the controls over this data, and tested some of those controls. We found L&I's prescription drug data to be sufficiently reliable for our audit purposes. We were able to summarize L&I's fiscal year 2009 prescription drug data into the categories shown in the table below (**Appendix C**). This table supports many of the issues discussed in the body of the report.

APPENDIX C: L&I DRUG PURCHASES

L&I Workers' Compensation Prescription Drug Purchases Including Dispensing Feeds Fiscal Year 2009				
Drug category	Expenses	Percent of total	Number of prescriptions	Percent of total
Brand-name with no generic therapeutic equivalents	\$11,280,542	37.7%	48,788	11.4%
Brand-name with generic equivalent, prescribed under carve-out per RCW 69.41.190	\$167,399	0.6%	781	0.2%
Brand-name with generic equivalent, prescribed under dispense as written per RCW 69.41.190	\$355,879	1.2%	1,712	0.4%
Brand-name dispensed when generic equivalent was allowed by provider	\$187,811	0.6%	1,192	0.3%
Generic	\$17,619,945	58.9%	373,896	87.5%
Other	\$293,380	1%	982	0.2%
Totals	\$29,904,956	100%	427,351	100%
Source: State Auditor's Office analysis of L&I's Workers' Compensation program FY09 prescription drug expenditures.				
Note: *Information reflects U.S. Food and Drug Administration drug definitions as of September 2010, when some earlier definitions changed. For example, some drugs that were not characterized as therapeutic equivalents during FY 2009 later received that designation. Therefore, the number of brand-name prescriptions with therapeutic equivalents could be slightly over stated. For example, the category "Brand-name dispensed when generic equivalent was allowed by provider" includes 47 drugs (3.9%) whose definition changed in September 2010.				

APPENDIX D: PILL-SPLITTING

In a 2006 article, Consumer Reports indicates that physicians have long counseled patients to split pills because of the limited number of fixed doses available from the manufacturers. The article further indicates that pills can be safely split for the following medicines as a way to save money:

- Amlodipine (Norvasc)
- Nefazodone (Serzone)
- Atenolo (Tenormin)
- Olanzapine (Zyprexa)
- Atorvastatin (Lipitor)
- Paroxetine (Paxil)
- Citalopram (Celexa)
- Pravastatin (Pravachol)
- Clonazepam (Klonopin)
- Quinapril (Accupril)
- Doxazosin (Cardura)
- Rosuvastatin (Crestor)
- Finasteride (Proscar)
- Sertraline (Zoloft)
- Levothyroxine (Synthroid)
- Sildenafil (Viagra)
- Lisinopril (Zestril)
- Simvastatin (Zocor)
- Lovastatin (Mevacor)
- Tadalafil (Cialis)
- Metoformin (Glucophage)
- Vardenafil (Levitra)
- Metoprolol (Toprol)

The article indicates that judgments about pills that can be safely split are best made by physicians.

This article also indicates that pill-splitting is not safe for chemotherapy drugs, anti-seizure medicines, birth control pills, blood thinners, capsules, pills with hard outside coatings, pills designed to release medication over time or throughout the day, pills that are coated to protect your stomach, and pills that crumble easily.

The entire article can be found at: <http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/money-saving-guides/english/PillSplitting-FINAL.pdf>

APPENDIX E: ANNUAL DRUG EXPENDITURES

Drug Expenditures by Agency, Fiscal Year 2009	
Agency	Total expenditures
DSHS/Medicaid/Health and Recovery Services	\$480 million
Health Care Authority/Uniform Medical	\$168 million
Health: Immunization Program – \$116 million HIV Client Services – \$12 million Total	\$128 million
Labor & Industries – Workers' Compensation Program	\$30 million
Corrections	\$12 million
Veterans Affairs	\$1 million
Total	\$819 million
Source: 2009 prescription drug expenditures reported by agency staff.	

APPENDIX F: PRESCRIPTIONS BY DRUG CLASS

L&I's Workers' Compensation Program Fiscal Year 2009 Drug Expenditures by Therapeutic Class		
Therapeutic class	Expenses	Percentage of total
Analgesics, Narcotics	\$7,386,824	25%
Anti-convulsants	\$4,349,143	15%
Nonsteroidal Anti-inflammatory Drugs (NSAIDs), Cyclooxygenase Inhibitor - Type	\$2,660,154	9%
Serotonin-Norepinephrine Reuptake-Inib (SNRIS)	\$2,255,088	8%
Skeletal Muscle Relaxants	\$2,221,104	7%
Selective Serotonin Reuptake Inhibitor (SSRIS)	\$1,278,282	4%
Anti-psychotics, Atypical, Dopamine, & Serotonin Antag	\$1,181,829	4%
Proton-Pump Inhibitors	\$822,958	3%
Anti-anxiety Drugs	\$677,308	2%
Anti-psychotics, Atyp, D2 Partial Agonist/5HT Mixed	\$656,721	2%
Norepinephrine And Dopamine Reuptake Inhib (NDRIS)	\$543,253	2%
Heparin and Related Preparations	\$542,311	2%
All Other Classes	\$5,329,982	18%
Total	\$29,904,956	100%
Source: State Auditor's Office analysis of L&I's Workers' Compensation program FY 2009 prescription drug expenditures Percentages do not add to 100 percent because of rounding.		

APPENDIX G: GLOSSARY

Average Wholesale Price (AWP): Refers to the average price at which wholesalers sell drugs to physicians, pharmacies and other customers. It is a figure reported by commercial publishers of drug pricing data, which is obtained from manufacturers, distributors and other suppliers. The AWP is often characterized as a “sticker price” or “list price,” as used in the automobile industry. It serves as a prescription drug pricing benchmark for payers throughout the health care industry. Payments are typically based on AWP minus some percentage.

Brand-name drug: A brand-name drug typically originates with a patent that legally protects the drug’s ingredients from being copied by other manufacturers. While patent protection exists, the manufacturer sells the brand-name drug free of competition. After the patent expires, the manufacturer typically continues to sell the brand-name drug but with competition from other drug manufacturers, including manufacturers of generics.

Carve-out: A statutory provision that enables physicians to prescribe brand-name drugs for certain specific conditions or ailments. Carve-outs exempt certain classes of drugs from the requirement that physicians prescribe low-cost drugs in place of more expensive ones.

Dispense-as-written: See Therapeutic Interchange Program.

Endorsing physicians and endorsing providers: See Therapeutic Interchange Program.

Generic drug: A copy of a brand-name drug whose patent has expired. A generic drug has the same active ingredient(s) as the brand-name drug it copies. The only difference is its price and appearance. Generics are much less expensive and, by law, may not look exactly like the brands they copy.

Opioids: Drugs that decrease the patient’s perception of, reaction to, and tolerance of pain. Physical dependence can develop with ongoing administration of opioids, leading to a withdrawal syndrome with abrupt discontinuation. Opioids are well known for their ability to produce a feeling of euphoria, which increases their potential for abuse.

Pharmacy and Therapeutics Committee: Plays a key role in the selection of drugs that are incorporated into the PDL. The PDL consists of drugs that have been reviewed by the Washington State Pharmacy and Therapeutics Committee and found to be safe and effective based on research conducted by the Oregon Health and Science University. Consistent with RCW 70.14.050, members of the Committee are selected by Labor and Industries, the Health Care Authority and DSHS. Current members include four doctors, four pharmacists, one physician’s assistant, and one nurse practitioner.

Pill-splitting: The practice of modifying a tablet, capsule or pill to obtain a lower dose of the active ingredient or to obtain multiple smaller doses. The practice is generally used to reduce the cost of a prescription or because the drug is not available in the desired dose. Often, pills that are meant to be split, such as aspirin, are scored so that they may be accurately and easily divided into halves or quarters.

Preferred Drug List (PDL): A list of drugs found to be clinically safe, effective and more economical than higher priced brand-name drugs for specific conditions. The PDL is described in detail beginning on page 16.

Prior authorization: A requirement in prescription drug programs that physicians or health care providers obtain approval from insurance providers or other health care payers before they prescribe and obtain payment for certain drugs, including those with high costs, questionable safety or effectiveness.

Private Benefits Manager: A third-party administrator of prescription drug programs who contracts with insurers, including state agencies, to process and pay prescription drug claims. L&I uses its PBM to develop and maintain its preferred drug list and to negotiate rebates with drug manufactures.

Therapeutic equivalent: Typically, a generic drug that has the same active ingredient(s) as a brand-name drug and is found to be equally safe and effective. In the U.S., the federal Food Drug Administration determines therapeutic equivalency.

Therapeutic Interchange Program: A program for Washington State physicians who write prescriptions for patients receiving benefits through L&I, the HCA or DSHS. Physicians who register with the TIP may prescribe brand-name drugs that are not on the PDL without prior approval by indicating dispense as written on the prescription form. Or they may allow pharmacists to dispense generic equivalents for brand-name drugs by indicating "substitution allowed." Physicians who have not registered as endorsing physicians must obtain prior authorization from L&I to prescribe non-preferred drugs.

STATE AUDITOR'S OFFICE CONTACTS

STATE AUDITOR BRIAN SONNTAG, CGFM

(360) 902-0361

BRIAN.SONNTAG@SAO.WA.GOV

LARISA BENSON

DIRECTOR OF PERFORMANCE AUDIT

(360) 725-9720

LARISA.BENSON@SAO.WA.GOV

MINDY CHAMBERS

DIRECTOR OF COMMUNICATIONS

(360) 902-0091

MINDY.CHAMBERS@SAO.WA.GOV

To request public records from the State Auditor's Office:

MARY LEIDER

PUBLIC RECORDS OFFICER

(360) 725-5617

PUBLICRECORDS@SAO.WA.GOV

GENERAL INFORMATION

Headquarters

(360) 902-0370

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