Introduction

Program Mandate

The Newfoundland and Labrador Prescription Drug Program (NLPDP) is operated by the Department of Health and Community Services and provides assistance in the purchase of pharmaceuticals and some related medical supplies to residents of the Province who qualify for benefit coverage. Drugs are dispensed mainly through the network of community pharmacies located throughout the Province.

Eligibility and **Benefit Details**

Assistance in the purchase of pharmaceuticals and some related medical supplies is provided to three main groups of residents: income support recipients, senior citizens and special needs patients. Clients of the income support and seniors programs can obtain prescribed drugs by presenting their valid NLPDP drug card to a pharmacy. Drugs and supplies for the special needs program are obtained directly from the Health Sciences Centre.

Figure 1 outlines the detailed eligibility requirements and benefits for these three groups.

Figure 1

NLPDP Eligibility Criteria and Benefits

Eligibility	Eligibility	Benefits	Co Pay
Category	Criteria		Deductible
Income Support Recipients	- Residents of the Province who qualify for full benefit coverage under the Department of Human Resources, Labour and Employment (HRLE)	100% coverage of drug cost for identified benefits including a 10% mark-up when ingredient costs exceed \$30	None
	- Persons of low income with high drug costs are eligible for drug card coverage either from HRLE or the integrated health authorities	Maximum dispensing fee, \$6.50 per prescription	
Senior Citizens	Residents of the Province who are registered for Old Age Security Benefits and who are in receipt of the Guaranteed Income Supplement	100% coverage of drug cost for identified benefits	Patient pays the dispensing fee and any other cost of drug in excess of the defined drug cost
Special Needs Patients	Residents with Cystic Fibrosis and Growth Hormone deficiency or specified metabolic disorders	100% coverage of identified benefits for disease related prescription drugs, medical supplies, food and equipment	None

Source: NLPDP records

Program Cost and Recipient Use

Figure 2 shows the costs, number of clients, and number of prescriptions for 2004 and 2005.

Figure 2

NLPDP Costs and Number of Clients Years Ended 31 March \$ Millions

Group	2004				2005		
	Costs	Clients	Prescriptions	Costs	Clients	Prescriptions	
Income support recipients	\$56.4	58,116	1,543,783	\$58.6	55,486	1,584,182	
Senior citizens	40.2	37,208	1,087,296	42.6	37,653	1,093,187	
Special needs patients	0.9	148	n/a	0.7	145	n/a	
Total	\$97.5	95,472	2,631,079	\$101.9	93,284	2,677,369	

Source: Province of Newfoundland and Labrador and NLPDP records $\ensuremath{\text{n/a}}$ - Not Applicable

Drug Usage Monitoring

The NLPDP routinely monitors drug usage by clients through:

- detailed and general statistical analysis of claims paid through its claims payment databases; and
- quarterly reviews of the more frequent users of narcotics and other controlled drugs that are prone to abuse.

Drug Usage Control

The Department of Health and Community Services controls overall usage by:

- approving the drugs which will be covered under the NLPDP;
- placing restrictions on clients who are considered to be potentially abusing the NLPDP; and
- requiring special authorization for certain, usually more expensive drugs that are covered by NLPDP.

Audit Objectives and Scope

Objectives

The objectives of our review were to:

- assess the adequacy of the Department of Health and Community Services' management practices relating to the NLPDP; and
- assess the adequacy of processes at the Department to identify and address drug abuse.

Scope

We completed our review of the NLPDP in September 2005. Our review covered the period 1 April 2002 to 31 March 2005.

Conclusions

Increasing Program Costs

In the last 9 years, the cost of the NLPDP has increased by 92%, or \$48.7 million, from \$53.2 million in 1997 to \$101.9 million in 2005. During the same time, the number of clients decreased from 112,206 to 93,284 (a 17% decrease); however, the number of prescriptions increased from 2,131,526 to 2,677,369 (a 26% increase).

Poor Management Practices

While new drug therapies, higher per capita drug usage and the Province's aging population are significant factors in the dramatic increase in drug costs, we are concerned that poor management practices are not ensuring that program costs are minimized. For example:

• Unlike other provinces there is no on-line, real-time claims system to provide necessary management information on a more timely basis.

- As a result of not having an on-line, real-time system, the Province is unable to take advantage of lower prices related to "deeming" drugs within therapeutic classes as having equal health benefits, thereby setting the price for that class at a lower or median level. Of the 19 drugs we sampled, the Province paid \$754,000 more for 2 drugs than it would have had it deemed the drugs in this class as having equal health benefits and a set class price. Another Atlantic Province was able to take advantage of such lower prices because they had the required systems in place.
- Unlike other provinces, the Department does not have a program to educate doctors on new drugs and does not provide information to each physician on their pattern of prescribing drugs relative to their peers.
- Because of the lack of cooperation from pharmacies regarding the provision of client information, the Department's ability to audit a sufficient number of pharmacies is severely diminished. There are 275 pharmacies in the Province; however, only 6 audits have been undertaken since 2002 and only 1 (no problems identified) had been finalized. Audits are an important way of checking for potential problems such as over billing.
- While there are some system controls in place which are intended to ensure the accuracy of amounts paid for drugs, we found errors in amounts paid for 2 of 19 drugs that we sampled.

No Legislative Framework

The NLPDP has a budget of approximately \$100 million, which is larger than many Government departments. Yet the program is the only one in Canada without specific legislation to guide its operations. We would expect such a framework to specify such things as the responsibilities and accountabilities of Government, pharmacies and doctors, as well as provide enforcement provisions. The presence of legislation would also provide information for the Members of the House of Assembly on the effectiveness of this Program.

Apparent Indiscriminate Prescribing an Issue for Over 16 Years

Prescription drug abuse in the Province is documented at least as far back as 1988. There are two components to the drug abuse problem, i.e. client abuse and indiscriminate prescribing by physicians. The following outlines what was done to try and deal with prescription drug abuse.

The Client

The Department has a system in place to address "double doctoring". The main focus of the system is to restrict the use of a drug card to a single pharmacy.

Our review identified that the Department currently only selects the top 20 clients determined by the number of different physicians visited and who also went to multiple pharmacies. The extent of the review may not be adequate since only 20 of the approximately 1,800 clients were selected. When we questioned as to why only 20 were selected, we were informed by one NLPDP official that the decision was based upon professional judgment and past experience, and determined as being adequate to detect abusers. However,

- we were informed by another NLPDP official that "...the process is sometimes placed on a lower priority level as a result of workload issues"; and
- we noted a comment in the final report of a Treasury Board/Pharmaceutical Services Joint NLPDP Review completed in 2004 that stated "efforts were decreased during the operation of the Prescription Monitoring Program and have not yet returned to previous levels due to human resource constraints."

We also found that cards are not always restricted by HRLE on a timely basis. In 6 of the 20 samples we reviewed, it took between 49 and 90 days to have the card restricted.

The Physician

No substantive measures were introduced to deal with suspected indiscriminate prescribing by a relatively small number of general practitioners until the health and safety concerns related to OxyContin became public.

Our review indicated a number of issues regarding the utilization of prescription drugs under the Program. For example:

- 11 general practitioners were on the list of the top 10 prescribers of narcotics and other controlled drugs during the period 1 April 2002 to 31 March 2005. These physicians were writing from 25 to 50 times as many prescriptions for these drugs as most of their peers and accounted for approximately \$560,000 (15%) of the approximately \$3.7 million spent each year related to narcotics and other controlled drugs.
- The Department was not proactive in dealing with the small number of general practitioners suspected of indiscriminate prescribing.

Although officials indicated that information on possible indiscriminate prescribing was provided to the Newfoundland Medical Board (now called the College of Physicians and Surgeons), the Board in the final OxyContin Task Force Report indicated that, due to the Board's interpretation of its legislation, "...it is limited in its ability to fulfill its mandate of public protection".

It was not until the public outcry related to OxyContin abuse that Government amended the *Medical Act* to provide the Board with more comprehensive powers and requirements to deal with issues identified regarding such things as indiscriminate prescribing by doctors.

Drug Cards Inadequately Controlled

Lack of controls over drug cards provides the potential for drug abuse. This is particularly the case for the manual drug cards that are prepared in the various Department of Human Resources, Labour and Employment (HRLE) district offices when a client services officer (CSO) issues cards after hours, or in emergency situations.

We found that:

Departmental policies regarding the control of manual cards are not being followed. Manual cards are left blank for the CSO to fill out. Because these cards could be easily misused, and abused, the HRLE policy manual has strict guidelines for their control. However, our review of two larger HRLE district offices indicated that:

- in one office there was no record of blank manual drug cards issued to professional staff;
- in two offices there was no record of blank manual drug cards on hand; and
- in one office there were inadequate controls over voided drug cards.

Inconsistent Eligibility Criteria

There are inconsistent criteria applied by HRLE and Integrated Health Authority (IHA) staff in issuing drug cards because of inconsistent policies for determining eligible client expenditures. We found one instance where a client was refused a drug card at a HRLE office but was approved for a card for the same time period at an IHA office.

Findings and Recommendations

1. Program Costs and Statistics

Introduction

In the last 9 years, the cost of the NLPDP has increased by 92%, or \$48.7 million, from \$53.2 million in 1997 to \$101.9 million in 2005. Figure 3 reports the actual costs and the original budget figures for the last 9 years by each of the program groups.

Figure 3

NLPDP Cost and Budget Amounts (000's)

Year	Income Prog		Senior Citizens Program		Special Prog		Total	
	Actual	Budget	Actual	Budget	Actual	Budget	Actual	Budget
1997	33,164	33,929	19,398	18,636	597	700	53,159	53,265
1998	30,943	31,312	20,557	20,036	583	700	52,083	52,048
1999	32,511	30,690	22,613	21,295	519	700	55,643	52,685
2000	35,968	34,796	24,533	24,256	521	700	61,022	59,752
2001	40,147	37,480	28,827	26,915	607	750	69,581	65,145
2002	46,544	42,678	32,373	28,918	656	600	79,573	72,196
2003	51,040	46,658	36,436	32,562	686	631	88,162	79,851
2004	56,378	56,079	40,234	39,704	853	640	97,465	96,423
2005	58,564	61,143	42,579	44,033	737	788	101,880	105,964

Source: Province of Newfoundland and Labrador public accounts

Cost Contributors

The Canadian Institute for Health Information (CIHI), in a number of reports on Drug Expenditure in Canada covering the period 1985 to 2003, indicated that spending on drugs was increasing significantly year over year despite the fact that drug prices in Canada have remained relatively stable. The reports attribute the increasing costs to:

- a higher volume of drug use; and
- the entry of new drugs, which are generally introduced to the market at higher prices.

Income Support Program Analysis The information in Figure 4 shows that there has been a significant increase in income support program drug costs over the past 9 years. This is despite the fact that the number of clients using the program has declined. The significant increase over the past 9 years is due to:

- increased drug usage (i.e. increase in number of prescriptions written while number of clients decreased); and
- increased cost of drugs (i.e. significant % increase in average cost of prescriptions and average annual cost per client).

Figure 4

NLPDP
Income Support Utilization / Cost Summary

Category	1996-97	2004-05	Increase (decrease)	%
Clients	78,419	55,486	(22,933)	(29.2)
Prescriptions	1,247,841	1,584,182	336,341	27.0
Total Program Cost	\$33.2 M	\$58.6 M	\$25.4 M	76.5
Avg. # Prescriptions/Client	15.9	28.6	12.7	79.9
Avg. Prescription Cost	\$26.61	\$36.99	\$10.38	39.0
Avg. Annual Cost/Client	\$423.37	\$1,056.12	\$632.75	149.5

Source: Province of Newfoundland and Labrador and NLPDP records

Senior Program Analysis The information in Figure 5 shows that there has been a significant increase in the seniors program drug costs over the past 9 years. This is due to:

- an increased number of clients using the system;
- increased drug usage (i.e. % increase in prescriptions higher than increase in clients); and
- increased cost of drugs (i.e. % increase in average cost of a prescription and the average cost per senior).

Figure 5
NLPDP
Seniors Utilization / Cost Summary

Category	1996-97	2004-05	Increase	%
Clients	33,658	37,653	3,995	11.9
Prescriptions	883,685	1,093,187	209,502	23.7
Total Program Cost	\$19.4 M	\$42.6 M	\$23.2 M	119.6
Avg. # Prescriptions/Client	26.3	29.0	2.7	10.3
Avg. Prescription Cost	\$21.95	\$38.97	\$17.02	77.5
Avg. Annual Cost/Client	\$576.39	\$1,131.38	\$554.99	96.3

Source: Province of Newfoundland and Labrador and NLPDP records

Special Needs Program Analysis The information in Figure 6 shows that the client base and cost associated with the special needs program (residents with Cystic Fibrosis and Growth Hormone deficiency or specified metabolic disorders) has remained relatively constant over the past 9 years.

Figure 6
NLPDP
Special Needs Utilization / Cost Summary

Category	1996-97	2004-05	Increase	%
Clients	129	145	16	12.4
Prescriptions	n/a	n/a	n/a	n/a
Total Program Cost	\$0.6M	\$0.7M	\$0.1 M	16.7
Avg. # Prescriptions/Client	n/a	n/a	n/a	n/a
Avg. Prescription Cost	n/a	n/a	n/a	n/a
Avg. Annual Cost/Client	\$4,651.16	\$4,827.59	\$176.43	3.8

Source: Province of Newfoundland and Labrador and NLPDP records n/a - Not applicable

2. Drug Costs

Introduction

The NLPDP establishes the maximum amount it will pay the pharmacies for the cost of prescription drugs whereas other provinces will reimburse pharmacies on the basis of their actual acquisition cost as established by the marketplace. Pharmacies submit a claim for the quantity of drugs dispensed and the NLPDP claims adjudication system applies the established maximum amount to arrive at the total amount to be paid. Maximum allowable amounts are:

- established for generic drugs on the basis of the solicitation of bids from generic manufacturers; and
- established for brand name drugs from manufacturers' published price lists.

Drug Cost Testing

We reviewed 19 drugs for the 2002-03 fiscal year to determine:

- how our costs compared to another Atlantic Province; and
- whether they were properly costed by the NLPDP.

We found that for 4 of the 19 drugs, the NLPDP costs were significantly higher than the other Atlantic province. These higher cost drugs included:

- two instances where drugs were purchased by the other Atlantic Province using a pricing strategy referred to as Maximum Allowable Cost; and
- two instances where the cost of drugs were higher because of undetected pricing errors in the NLPDP costing system.

No Proactive Pricing Strategy Results in Higher Drug Costs

Several provinces use a proactive pricing strategy called "Referenced Based Pricing" or "Maximum Allowable Cost" where:

- the cost that will be paid by the public programs to the pharmacy is based on the cost of particular drug(s) in a given category; and
- these drugs are deemed to be of equal health benefit as other drugs in the same therapeutic class, thereby setting the price at a lower or median level.

Using NLPDP drug volumes for the period 2002-03, and the lower unit drug costs of a comparative Atlantic Province, we estimated that the NLPDP would have saved an estimated \$754,000 for the two drugs (Vioxx and Celebrex) included in the sample if it had been able to use the maximum allowable price.

NLPDP officials advise that they have not been able to avail of proactive strategies such as Referenced Based Pricing because the claims payment system is not on-line and real-time. Therefore, the pharmacist would not have the necessary information to use Referenced Based Pricing.

Drug Cost Errors

One of the pricing errors involved a generic drug:

- where the generic manufacturer had not bid its lowest price for a drug for the period March 2002 to March 2004; and
- that resulted in an overpayment for this drug of approximately \$23,348.

The other pricing error involved a brand name drug:

- that was included in the payment system at a more expensive wholesale drug price rather than at the direct manufacturer's price for the period November 2001 to March 2004; and
- that resulted in an overpayment for this drug of \$4,500.

In addition, we noted the errors for these two manufacturers affected other drugs they supplied and resulted in an overall error of approximately \$79,000.

As well:

- there are no systems in place to ensure that generic manufacturers are bidding the lowest prices;
- the NLPDP does not carry out unit cost comparisons to other provinces as a process for identifying drug cost differences; and
- these overpayments were not recovered nor are they expected to be recovered from the pharmacies involved.

3. Prescription Drug Utilization - Prescribing Issues

Introduction

The policies, procedures and methods in place to ensure the best patient and financial outcomes from prescription drug therapies vary from one province to another. In order to assess and compare the NLPDP to other provinces and best practices we:

- reviewed information obtained from the other jurisdictions across Canada;
- examined the Department's evaluation report dated May 2004 on the Prescription Monitoring Program (PMP) Pilot program which was in place from June 2000 to March 2002;
- examined the final report of a Treasury Board/Pharmaceutical Services Joint NLPDP Review carried out during the period July 2003 to March 2004; and
- interviewed NLPDP and other Departmental officials.

Direct Marketing

It is clear from a review of various reports and from discussions with NLPDP officials that the marketing of drugs directly to physicians is an important strategy used by the various drug companies to increase and maintain market share. Much of this direct marketing activity relates to the introduction of new drugs and may take many forms such as:

- visits to physicians' offices;
- direct advertising;
- the provision of personal incentives to physicians; and
- the provision of sample drugs for distribution to patients without cost.

In order to counteract any potential undue bias towards the use of more costly and/or less effective drugs as a result of these practices, other provinces have implemented educational and other programs such as:

- "Academic Detailing"; and
- prescribing pattern and peer comparison feedback.

"Academic Detailing"

This program, presently in use in a number of other provinces, is a proactive effort to improve prescribing practices by providing physicians with complete and objective drug information based upon the best available evidence. The process involves qualified health care professionals making periodic, short visits to a physician's office to discuss therapeutic issues, usually around a specific drug.

The NLPDP does not have a similar program to educate physicians.

Physician Feedback

According to NLPDP officials, in other provinces, the provision of feedback to physicians about their prescribing patterns has proven to be an effective tool in improving patient outcomes and containing escalating drug costs. Feedback programs normally:

- provide feedback to physicians about their prescribing patterns;
- compare their prescribing patterns to peers; and
- compare their prescribing patterns to best practice.

The NLPDP accumulates the necessary data in its claims payments system to provide feedback; however, there is no program in place to provide this feedback to physicians.

Sampling

While the benefits to the manufacturer related to the use of samples appear to be fairly clear, the advantages and disadvantages to other stakeholders vary. The main advantages tend to focus around the fact that the drugs are made available free of charge. The disadvantages tend to focus on the lack of control over samples inventories and the fact that sample drugs are not entered into the patients' medication history at a pharmacy.

Since the issuance of sample drugs is not an area controlled or paid for by the NLPDP, efforts to implement controls would involve all of the stakeholders including the Newfoundland and Labrador Medical Association, the Pharmacists' Association of Newfoundland and Labrador and the NLPDP.

4. Prescription Drug Utilization - Abuse

Introduction

Prescription drug abuse involves the inappropriate personal use of, or the diversion of some prescription medications for illicit uses, "mainly sale on the street". The role of NLPDP officials in the detection and control of prescription drug abuse centers around:

- their responsibility to provide advice to the Department's executive on health policy and other issues related to the practice of pharmacy in the Province; and
- their specific responsibilities as the managers of the publicly funded prescription drug programs.

Figure 7 shows the top 10 drugs dispensed from the monitored list for the fiscal year 2004-05.

Figure 7

NLPDP Income Support Program

Top 10 Drugs Prescribed From the Monitored List
2004-05

#	Drug	Туре	Common Usage	# Rx	Total Cost
1	ATASOL 30	Analgesic with codeine and caffeine	Pain Killer	27,601	\$ 257,693
2	Methadone Compounds	Narcotic	Treatment of Opiate drug addiction	9,005	79,322
3	Demerol Tablet 50 mg	Narcotic analgesic	Pain killer	8,343	100,745
4	APO Diazepam 10 mg	Benzodiazepine	Mood altering drug	7,033	90,717
5	APO Lorazepam 1.0 mg	Benzodiazepine	Mood altering drug	6,723	60,802
6	GEN Zopiclone 7.5 mg	Hypnotic	Sleeping pill	6,157	136,275
7	NOVO Lorazem 1.0 mg	Benzodiazepine	Mood altering drug	5,797	52,220
8	PMS Temazepam 30 mg	Benzodiazepine	Sleeping pill	5,567	58,090
9	PMS Clonazepam-r 5 mg	Benzodiazepine	Treatment of seizure disorders	5,160	72,771
10	PMS Methylphenidate 10 mg	Stimulant (i.e.Ritalin)	Treatment of attention deficit disorder	5,123	103,343
	Total			86,509	\$1,011,978

Source: NLPDP claims files and other records

Narcotics and Other Controlled Drugs

NLPDP officials:

- have identified a list of narcotics and other controlled drugs that they consider prone to abuse;
- review on a quarterly basis prescription drug usage for drugs included in the monitored list; and
- have determined that most of the abuse of prescription drugs can be attributed to clients on the Income Support Program.

Prescription Monitoring Program

The NLPDP has systems in place to identify and address abuse situations with its own clients and it also addresses abuse issues identified as a result of information from public sources. In June 2000, the Newfoundland Medical Board implemented a Provincial government funded, Provincewide pilot Prescription Monitoring Program (PMP) for narcotics and other controlled drugs. This program had been used in other provinces and was a very comprehensive program that:

- was set up to test its effectiveness in combating the abuse of narcotics and other controlled drugs;
- was in place for the period 19 June 2000 to 31 March 2002;
- relied on batch prescription drug information transmitted electronically by the various pharmacies to the PMP office for analysis;
- used a system of "alert" and "explain" letters to physicians to address individual cases of potential abuse;
- monitored drugs dispensed to the general public as well as those dispensed under the publicly funded programs; and
- monitored a list of controlled drugs generally accepted as prone to abuse.

The Department's evaluation report dated May 2004 on the Prescription Monitoring Program (PMP) Pilot program:

- noted that, "contrary to legislation, at least 11 pharmacies failed to report data";
- noted that, "some high prescribing physicians identified by the Province's drug subsidy program were located near these pharmacies";
- commented that, "professional regulatory groups appeared unable to accommodate the financial and legal risks necessary to address suspected inappropriate behavior among physicians, pharmacists and patients"; and
- recommended targeted peer prescribing reports, academic detailing and regulatory sanctions to replace the PMP; however, at the time of our review in September 2005, these recommendations had not been fully addressed.

This program was discontinued because it did not impact: the prescribing of program monitored drugs; identified substitutes; and the incidence of double doctoring as expected.

Impact of Abuse on NLPDP Costs

Figure 8 shows the total cost of prescription drugs dispensed from the list of monitored drugs for the income support program over the last three years compared to the total cost of all prescriptions dispensed under this program. Drugs dispensed from the monitored list:

- have averaged approximately \$3.7 million per year or 6.6% of all drugs dispensed under the program; and
- for the top 100 users cost approximately \$500,000 per year. This would be an indication of the amount subject to abuse.

Figure 8

NLPDP Income Support Program Drug Costs 31 March

Drug Category	200)3	200)4	200)5	Tota	ıl
	\$	%	\$	%	\$	%	\$	%
Monitored list	3.3 M	06.5	3.9 M	06.9	3.8 M	06.5	11.0 M	06.6
Other	47.7 M	93.5	52.5 M	93.1	54.8 M	93.5	155.0 M	93.4
Total	51.0 M	100.0	56.4 M	100.0	58.6 M	100.0	166.0 M	100.0

Source: Province of Newfoundland and Labrador and NLPDP records

Individual and Community Impacts of Abuse The actual impact of prescription drug abuse upon individuals and the community at large is difficult to determine. Much of the available information is anecdotal, based upon discussions with law enforcement and other officials. However, the information included in the 30 June 2004 OxyContin Task Force Final Report as well as the Department's evaluation report dated May 2004 on the Prescription Monitoring Program (PMP) Pilot program provides a good indication as to negative individual and community impacts related to OxyContin that in many ways would be applicable to other drugs also included in the monitored list. Some of the impacts noted in the OxyContin and PMP evaluation reports included reference to:

• 20 deaths during the period 1997 to 2004 attributed to drug ingestion with 8 of these related to OxyCondones mostly in combination with other drugs;

- armed robberies;
- shoplifting rings in place to support drug habits; and
- increased prescription drug abuse in schools.

A. Potential Indiscriminate Prescribing

Long Term Prescription Drug Abuse

Information obtained during our review shows that prescription drug abuse, mainly in the urban areas of the Province, has been a problem for many years.

For example, a 1988 internal study carried out by the Medical Care Program (MCP) on physician over-servicing and patient double doctoring in the St. John's area identified 428 patients who received excessive physician services either for no apparent reason or so they could obtain narcotics. MCP found that:

- patients did not tell the physician that they had received a prescription for narcotics in the prior 30 days. There was reference in the Department's evaluation report dated May 2004 on the Prescription Monitoring Program Pilot program that because of legal concerns around confidentiality, MCP was reluctant to initiate a police investigation;
- a common group of general practitioners in the St. John's area had seen each of the identified patients at least once; and
- police informants identified the same physicians as "known" sources of inappropriate prescriptions.

Prescriptions Written for Monitored Drugs Figure 9 displays the number of prescriptions written by physicians for drugs on the monitored list. Specifically, the Figure shows that 10 of the approximately 1,100 physicians continually write from 25 to 50 times as many monitored drug prescriptions as the majority of their peers.

Figure 9

NLPDP Income Support Program

Monitored Prescription Drug Ranges
As at 31 March

# Prescriptions	20	003	20	004	20	005	To	otal
_	Drs	%	Drs	%	Drs	%	Drs	%
1 to 100	712	64.20	739	63.93	751	67.11	2,202	65.07
101 to 500	284	25.61	294	25.43	272	24.31	850	25.12
501 to 1,000	71	06.40	75	06.49	53	04.73	199	05.88
1,001 to 2,500	32	02.89	39	03.37	33	02.95	104	03.07
2,501 to 5,000	10	0.90	8	0.69	8	0.72	26	0.77
5,001 to 10,000	0	0	0	0.00	1	0.09	1	0.03
Over 10,000	0	0	1	0.09	1	0.09	2	0.06
Total	1,109	100.00	1,156	100.00	1,119	100.00	3,384	100.00

Source: NLPDP income support claims database

Prescribers of Concern

Figure 10 shows the top 10 prescribers of drugs on the monitored list over the past three years. In summary:

- a total of 14 physicians have prescribed the most drugs on the monitored list over the past 3 years;
- 3 of the 14 physicians are psychiatrists;
- 11 of the 14 physicians are general practitioners; and
- 7 of the 14 physicians were on the top 10 prescribers of drugs for each of the three years.

Figure 10

NLPDP Income Support Program
Top 10 Prescribers
Fiscal Year Ended 31 March

	2003	3		20	04		20	05
Phy	sician	Rxs	Phys	sician	Rxs	Phys	sician	Rxs
Id	Type		Id	Type		Id	Type	
A	Gp	4,761	G	Gp	11,724	G	Gp	11,037
В	Gp	4,679	A	Gp	5,604	N	Psy	9,074
С	Gp	4,214	В	Gp	5,022	В	Gp	4,625
D	Gp	3,778	D	Gp	4,528	A	Gp	4,571
Е	Psy	3,632	С	Gp	3,930	С	Gp	4,405
F	Gp	3,463	F	Gp	3,579	D	Gp	3,985
G	Gp	3,311	Е	Psy	3,478	F	Gp	3,468
Н	Gp	2,951	K	Gp	2,911	M	Gp	3,402
I	Gp	2,908	J	Gp	2,857	Е	Psy	3,397
J	Gp	2,843	L	Psy	2,816	L	Psy	3,035

Source: NLPDP Income Support claims database Gp-General Practitioner, Psy-Psychiatrist

The average cost of drugs prescribed from the monitored list under this program over the past three years by these physicians was approximately \$660,000, with \$560,000 of this amount being prescribed by general practitioners.

With respect to prescribing practices:

- most health and law enforcement officials have been aware that a small number of physicians have been prescribing a large portion of drugs on the monitored list at least as far back as the MCP review of 1988;
- information contained in the Department's evaluation report dated May 2004 on the Prescription Monitoring Program Pilot program that covered private as well as publicly funded clients, is consistent with the information in Figures 9 and 10;
- Department officials have been concerned about this unusual behavior of this small group of physicians and advise that the Newfoundland Medical Board (NMB) has been made aware of the situation many times, however;

- commentary in the OxyContin Task Force Report indicated that the Newfoundland Medical Board believed that due to the Board's interpretation of its legislation, "it is limited in its ability to fulfill its mandate of public protection"; and
- NLPDP officials could provide no documentation that the NMB had been asked to carry out a thorough and complete investigation of the frequent prescribers of monitored drugs until October-November 2005. This request was made in relation to amendments to the *Medical Act 2005* assented to 19 May 2005.

As a result, the situation has existed for at least 16 years without being adequately addressed.

Dispensing Activity

There are approximately 275 pharmacies that dispense drugs to clients of the NLPDP across the Province. Figure 11 shows the 10 pharmacies that dispensed the most prescription drugs from the monitored list to income support clients for the last three years. 12 pharmacies have been in the top 10 dispensers over the past 3 years, with 8 of the 12 pharmacies on the top 10 dispensers of drugs for each of the three years.

Figure 11
NLPDP Income Support Program
Top 10 Pharmacies
Fiscal Year Ended 31 March

20	03	20	04	20	05
Pharmacy	Rxs	Pharmacy	Rxs	Pharmacy	Rxs
A	8,520	Е	11,764	Е	9,686
В	6,343	C	7,126	I	9,385
С	6,287	D	6,311	С	6,393
D	6,152	В	6,051	D	6,364
E	5,734	F	5,632	F	6,166
F	5,106	A	4,842	В	5,559
G	4,652	G	4,692	L	5,497
Н	4,480	J	4,401	G	4,330
I	4,149	I	4,218	A	4,215
J	3,915	K	4,206	K	4,194

Source: NLPDP Income Support claims database

Two of the 11 pharmacies that refused to participate in the PMP are included in those noted in Figure 11. While we did not attempt to relate the location of pharmacies in Figure 11 to the offices of the highest prescribing physicians in Figure 10, it is evident that some of the high prescribing physicians were located in or near the locations of the top 10 pharmacies.

B. Client Abuse Review Process

Introduction

Claims for reimbursement of prescription drugs by the various community-based pharmacies are processed through the Newfoundland and Labrador Prescription Drug Program claims payment system operated by Xwave. Monitoring activity for drug abuse in recent years has consisted of the quarterly Drug Utilization Review (DUR) carried out by NLPDP officials. This report is prepared from information extracted for the income support and seniors claims databases. The current criteria for inclusion on the quarterly report are that the:

- client received 2 or more prescriptions from the DUR list of controlled drugs; and
- prescriptions were written by 2 or more physicians; and
- prescriptions were dispensed at 2 or more pharmacies; and
- client is not currently under an initial review or being carried forward for review as a result of monitoring during the last 12 months.

Adequacy of Drug Card Restrictions

When a review of the client's drug history indicates the possibility of abuse, the usual intervention would be to restrict the client to one pharmacy of his or her choice. NLPDP officials advise that there are approximately 200 clients restricted to one pharmacy in any three month period. This restriction ensures that one professional pharmacist is aware of all of the drugs a client is receiving from the public plan and can intervene if continued abuse is suspected. Also, as a part of this process:

- a letter along with the medication history is sent to any physicians who have prescribed to the client during the last 12 months; and
- officials at HRLE are advised to collect the existing unrestricted drug card and issue a restricted drug card.

We examined 20 clients who had been reviewed for possible drug abuse and whose drug cards had been restricted. We found that it took between 49 and 90 days to have restrictions put in place for 6 of the 20 clients.

Therefore, the long period of time required to put the restriction in place extends the time the potential abuse can continue.

Adequacy of NLPDP Abuse Detection

We also noted from our testing of the 20 samples that potential drug abusers can be on the DUR for considerable time before being reviewed for abuse. For example, of the 20 samples tested:

- 4 were on the DUR greater than 9 quarters before being reviewed;
- 4 were on the DUR for between 5 and 8 quarters before being reviewed;
- 6 were on the DUR for between 3 and 4 quarters before being reviewed; and
- 6 were on the DUR for 2 quarters or less before being reviewed.

Since the October - December 2004 quarter, the focus of the DUR has been on the 20 clients who use the most physicians and the most pharmacies to obtain drugs from the monitored drug list. In addition, other reviews are carried out as a result of information from complaints or other sources. The adequacy of the review is difficult to determine since any client using two or more physicians and two or more pharmacies has the potential for abuse. Figure 12 shows the ranges of clients for a sample quarterly drug utilization report.

Figure 12

NLPDP Income Support Program

Drug Utilization Report ranges

Ouarter # 4 - 2003

Range	# Clients	# Doctors	# Pharmacists
1	Top 20	7-16	3-8
2	16	7	2-5
3	25	6	2-6
4	50	5	2-10
5	120	4	2-8
6	266	3	1-6
7	555	2	1-5
8	799	1	1-5
Total	1,851		

Source: NLPDP records

Figure 12 shows that 1,831 of the clients using multiple doctors and/or pharmacies may not be reviewed. Of these, 1,044 had used at least 2 doctors and 2 pharmacies. During the process of our review we were advised by one NLPDP official that the decision to review the 20 top clients was based upon professional judgment and past experience, and determined as being adequate to detect abusers. However,

- we were advised by another NLPDP official that "the process is sometimes placed on a lower priority level as a result of workload issues"; and
- we noted a comment in the final report of a Treasury Board/Pharmaceutical Services Joint NLPDP Review completed in 2004 that stated; "efforts were decreased during the operation of the Prescription Monitoring Program and have not yet returned to previous levels due to human resource constraints."

Therefore the extent of the review may not be adequate.

5. Claims Audits

Audit Services Division Involvement

The Audit and Claims Integrity Division of the Department of Health and Community Services is located in St. John's and initiates claims audits on pharmacies flagged as a result of:

- unsatisfactory responses from pharmacy and client confirmation and inquiry letters sent by Xwave;
- third party complaints;
- ongoing analysis of claims billing data;
- specific areas of concern identified during audits;
- follow-up audits; and
- audits of newly registered pharmacies.

Physical Audit Strategy

The audit strategy used to resolve questions arising from claims processing and to carry out other investigations:

- is influenced significantly by the fact that at any point in time there are some 275 pharmacies all across the Province that submit claims:
- relies heavily on the practice of requesting pharmacies to send photocopies of prescriptions and other documentation through the mail or by fax to the Audit and Claims Integrity Division office in St. John's for review in order to identify pharmacies with issues requiring audit; and
- relies on photocopies of prescription and other documentary evidence to support audit findings that result in recoveries from the pharmacies.

Impact of Audit Restrictions

As a consequence in 2002 of the pharmacies' refusal to provide photocopies of documents:

- Only 6 audits have been undertaken since September 2002, 5 of which have not been completed. There were no problems identified in the 1 audit which was completed.
- Queries arising from confirmation letters and similar investigative procedures have not been consistently followed up or resolved since September 2002, therefore the ability to ensure the validity of some of the claims may not now be possible because the legal requirement to retain original prescription forms is only two years.

Finalization of Audits Placed on Hold

There have been 5 comprehensive audits carried out between October 2004 and 2005, and 1 was carried out in 2003. Issues and irregularities identified in the 5 ongoing audits included:

- split prescriptions (results in more prescription fees);
- no supporting prescription;
- unauthorized repeats of prescriptions;
- quantities dispensed and billed exceeded quantities prescribed;
- expired prescriptions filled;
- claims billed in error; and
- claims credited on the store system but not credited to the NLPDP.

The dollar value of these errors and irregularities were significant. For example, we were advised by audit staff that 1 of the 5 audit files placed on hold involved questionable overbillings totaling approximately \$85,000.

Officials advise that these audits have not been brought to a conclusion where overpayments are recovered because they do not have authority from the Department's executive to proceed.

Other

In addition to their responsibilities related to the audit of prescription drug claims, the Audit and Claims Integrity Division has responsibility for the audit of MCP claims.

Officials indicated that since October 2004 the Division researched two cases to test the Department's new Cabinet authority to provide information to the police for clients suspected of double doctoring.

Although Division officials advise that double doctoring is suspected in these two cases, as at December 2005 the information had not been provided to the police. Officials indicated that the files were not sent to the police pending an opinion by the Department of Justice as to the appropriateness of the information. This opinion was requested in July 2005; however, the opinion, indicating that the information was appropriate to provide to the police, was not received until November 2005.

6. Manual Drug Cards

Introduction

Manual drug cards are issued:

- usually after regular office hours by client service officers (CSO) at the district offices of HRLE;
- mainly in the case of emergencies for a one day period; and
- to client and non client residents of the Province, many times without a financial assessment.

Manual Card Policies and Procedures

The manually prepared drug card is a 3 part "one write" form.

Policies and procedures in place to direct the issuance of cards and the control over blank manual drug cards are included in the HRLE Income Support Policies and Procedures Manual. These policies and procedures, which reflect the risks of abuse associated with this type of card, include:

• the designation of the district manager or another worker (distributor) to receive and assume control over drug card forms and print stock;

- provisions for the distributor to maintain detailed records of card numbers, workers to whom cards are issued and the date of issue;
- duties to be carried out by the CSO receiving blank manual cards;
- procedures to be used to control voided cards;
- a requirement for the distributor to send the recording copy of the card to NLPDP daily; and
- provision to ensure blank manual cards are stored in a secure area.

Policy Compliance Review

We reviewed practices in place at the Mount Pearl and the St. John's, Water St. HRLE Offices.

At the time of our initial visit in February 2005 to the Mount Pearl district office:

- the person filling the distributor function advised that they did not put a record in place to control the blank manual drug cards until 5 January 2005;
- the distributor did not have an inventory of blank manual cards when they assumed responsibility from the previous distributor and did not have a current record of the blank manual card numbers on hand; and
- there were 14 voided district office computer cheques in a "client accessible" reception work station and not all copies were present and of those that were, some were not marked as "void".

At the time of a second visit in October 2005 to the Mount Pearl district office:

- a new person had been assigned the distributor function;
- the person filling the distributor function advised that they did not continue to maintain a record to control the blank manual drug cards;

- the distributor did not have an inventory of blank manual card numbers when they assumed responsibility from the previous distributor and did not have a current record of the blank manual cards on hand;
- cards used by CSOs are not returned to the distributor to be sent to Xwave for recording in the system; and
- the distributor assumes the recording copy of the manual drug cards are being sent to NLPDP by the CSOs.

At the time of our visit in October 2005 to the St. John's Office:

- the distributor did not have an inventory count of blank manual cards when they assumed responsibility from the previous distributor;
- the distributor did not have a record of all of the card numbers on hand;
- cards used by CSOs are not always returned to the distributor to be sent to Xwave for recording in the system;
- the distributor assumes the recording copy of some of the manual drug cards are being sent to NLPDP by the CSOs; and
- the distributor advised that the blank manual forms provided to on call CSOs are retained in a common brief case that is simply passed on to the next CSO that is on call.

Inconsistent Eligibility Criteria

Eligibility criteria for support in the purchase of prescription drugs and supplies are not consistent. Inconsistent criteria is evidenced by the fact that:

- the HRLE income support financial assessment criteria are different than the Integrated Health Authority (IHA) enriched needs financial assessment criteria; and
- clients receiving drugs in emergency situations are not subjected to a financial assessment.

An example of the inconsistent criteria is where one of the applicants we reviewed was approximately \$300 - \$400 over the HRLE income level criteria to be eligible for a drug card, but was eligible when assessed for the same period by the IHA district office.

7. Legislation, Policies and Procedures

Legislative Authority

Newfoundland and Labrador is the only jurisdiction in Canada that does not have legislative authority to establish programs to provide drugs listed on the benefit listing to eligible beneficiaries.

The NLPDP is a large operation with a budget of approximately \$100 million which is significantly larger than many government departments. It:

- operates under the authority of the Minister of Health and Community Services;
- has no program specific accountability to the House of Assembly;
- administers the Newfoundland and Labrador Drug Products Formulary under *The Pharmaceutical Association Act 1994*; and
- last negotiated a written agreement with the Newfoundland and Labrador Pharmacists' Association in 1993.

Policies and Procedures

The NLPDP is a complex program, as evidenced by the fact that:

- it uses an independent contractor to process all claims and to perform other activities;
- the determination of eligibility and the issuance of drug cards for the Income Support program rests with the Department of Human Resources, Labour and Employment and various Integrated Health Authorities;
- it has a comprehensive special authorization program; and
- it has many exceptions and regulatory requirements.

Despite the complexity of the program, there is no comprehensive policy and procedures manual to direct all aspects of its operations.

Recommendations

The Department of Health and Community Services should:

- be more proactive in ensuring that program costs are minimized;
- resolve the issues with the Pharmacists' Association of Newfoundland and Labrador and reinstate the complete claims audit process;
- consider developing legislation for introduction in the House of Assembly to guide all aspects of the NLPDP;
- continue to address double doctoring by clients and suspected indiscriminate prescribing by physicians; and
- work with the Department of Human Resources, Labour and Employment and the Integrated Health Authorities to ensure consistent criteria are applied in issuing drug cards.

The Department of Human Resources, Labour and Employment should comply with policies established to control manual drug cards.

Department of Health and Community Services' Response

I share some of your opinions and recommendations, which are consistent with many of the initiatives in progress within the Department at this time. I will respond to your conclusions in the order they appear in your report.

Increasing Program Costs and Poor Management Practices

You have noted the increasing cost of the NLPDP is partly due to new drug therapies, higher per capita drug usage, and the increasing number of certain client groups. You have also suggested the introduction of certain management practices may assist in containing the growth of that cost. The Department is improving management practices by way of the following:

- 1) Introduction of an On-line Real-time adjudication system for the NLPDP: The Department issued a Request for Proposals on December 15th, 2005 for a new on-line real-time adjudication system for the NLPDP. Implementation of this system, targeted for Fall 2006, will enable us to examine other control measures you noted in your report, such as maximum allowable cost/reference based pricing.
- Reinstatement of the Audit process: The Department has made great efforts over the past three years to resolve issues with conducting audits. The Department remains committed to working with the Pharmacists' Association of Newfoundland and Labrador to address their concerns, while maintaining the integrity of the audit program. By way of example, Government established an Ad-hoc Working Group of the Pharmaceutical Services Liaison Committee to discuss audit issues and is committed to continuing this forum to discuss further issues.
- 3) Audits in progress: It should be noted that the completion of audits during your review period were restricted as a result of a conflict in policy. Audits in progress from January 2005 to October 2005 were suspended due to a dispute regarding the days supply policy for NLPDP prescriptions. This policy issue was resolved in October 2005, allowing the audits to proceed to the next stage in the process.
- 4) **Development of a Best Practices Network:** Best practices such as Academic Detailing and Physician Profiling are being used in other jurisdictions. While published evidence to support their costeffectiveness is limited at this time, they are widely accepted and viewed as positive interventions in facilitating optimal drug prescribing. The Department has been exploring options for development of a 'best practices network', to address quality in prescribing, and will keep your recommendations in mind as we consider options for future implementation.

Lack of Legislative Framework

You noted in your report the NLPDP is the only program in Canada without specific legislation to guide its operations. Draft legislation to govern Pharmaceutical Services in this province, including NLPDP, is targeted for the Fall Session of 2006. As such, we will be reviewing legislation in place in other provinces in the coming months, to ensure we have an appropriate level of legislation concerning the NLPDP.

Apparent Indiscriminate Prescribing and Client Abuse

In your report, you raised issues with apparent indiscriminate prescribing and client abuse of certain prescription drugs. The Department has implemented or is in the process of implementing the following to address these concerns:

- 1. The Department has recently adopted a quarterly reporting process where prescribing physicians that appear to be outside the norm with respect to prescribing of controlled substances will be reported to the College of Physicians and Surgeons of Newfoundland and Labrador for investigation. The first report to the College was made in November 2005.
- 2. A new Medical Act was proclaimed July 1, 2005 to address the deficiencies that had been noted with respect to this organization's past ability to appropriately investigate physician's practices and take disciplinary action when problems deserving of sanction are found. It is expected that this will enable the College to take necessary and appropriate action in response to any complaints received, including those from the Department of Health and Community Services.
- 3. Tamper Resistant prescription pads: The Department introduced a mandatory requirement for all physicians, dentists, and veterinarians to use specific prescription pads for the prescribing of specified narcotics, stimulants and barbiturates. These pads are pre-numbered and replenishing stocks are provided and controlled by the Department. This new requirement is working relatively well and is supported by the regulatory and professional bodies for medicine, dentistry, veterinary medicine, and pharmacy.
- 4. With respect to concerning beneficiary activity, the Pharmaceutical Services Division and Audit and Claims Integrity Division have established a joint Drug Utilization Review (DUR) Program to improve past efforts in this area. While not all beneficiaries of potential concern can be reviewed, staff are monitoring the results of their efforts to ensure the initiative is properly resourced. In addition to this process, the implementation of our real-time adjudication system, which will have on-line DUR capability, should enhance our current efforts in this area.

Inconsistent Eligibility Criteria

With respect to varying eligibility criteria in place within the Health Authorities and the Department of Human Resources Labour and Employment regarding the issuance of drug cards, we have noted your recommendation and will consider it in our future planning regarding the NLPDP.

Department of Human Resources, Labour and Employment's Response

In your report, you referenced that it took HRLE between 49 and 90 days to restrict a drug card issued by the Department. Restricting drug cards is an important control that the Department takes seriously. Once we have been notified by NLPDP that a drug card needs to be restricted, we make every effort to contact the recipient to have the existing drug card returned so it can be cancelled and a restricted card issued. Unfortunately, it is not always possible to have the active drug card returned, leaving the Department no choice but to wait until the active card expires, at which time a restricted drug card can be issued. Drug cards are usually only active for a one month period, however, the drug cards can be active for a period up to 6 months. Direction from NLPDP requires that the Department not cancel a drug card unless it is physically retrieved and manually cancelled. Consequently, in many situations, waiting for the existing card to expire is the only option available to our staff. When the new on-line real-time claims system is implemented, administrative procedures could be in place to restrict an active card immediately.

In the section "Drug Cards Inadequately Controlled" you referenced that "manual cards are left blank for the Client Services Officer to complete". Manual drug cards are usually used in after hours situations in order to provide drug card coverage in emergency situations. The covering period of the drug cards is usually limited to one day. Our direction in relation to ensuring adequate controls is clearly outlined in the Income Support Policy and Procedures Manual. In light of the findings in the preliminary draft of the Auditor General's Report, District Office management have been made aware of the control issue and steps have been taken to improve the situation.

Specific administrative staff have now been assigned the responsibility for the control of the manual drug cards. Each district office has an official book where all manual drug cards are recorded, and signed out to the appropriate Client Services Officer on call. The Department is working on a new approach to the delivery of "out of hours" services that would see specific staff provide this service in the district office. Working in a district office would mean having access to our computer system to confirm eligibility and would provide greater control and accountability.

In the section "Inconsistent Eligibility Criteria", there is a concern about different criteria used to determine eligibility for a regular drug card when a person is not in receipt of Income Support Benefits. As you are probably aware, under our former legislation, the Social Assistance Regulations, there was legislated authority to provide a more enhanced eligibility criteria for services and benefits to a specific group of individuals, namely individuals who require supportive services. In the late 1990's, this service was transferred to the Department of Health and Community Services. When an individual not in receipt of Income Support Benefits applies for a drug card because of high prescription drug costs, the eligibility criteria used by HRLE is legislated under the Income and Employment Support Regulations. In many instances, these individuals are deemed ineligible for the regular drug card. However, if the Client Services Officer discovers that this person is a 'person requiring' supportive services', the applicant is referred to the Integrated Health Authority to be assessed under their Enriched Needs policy. In some instances, because the eligibility criteria are different, the individual may be eligible for a drug card through the Department of Health and Community Services.

I would suggest that the reference that there are inconsistent criteria is not accurate per se, as there are different sub-programs within the NLPDP. Integrated Health Authorities and the Department of Human Resources, Labour and Employment service different client groups under 65 years of age, and do use different criteria. However, HRLE applies consistent criteria to its client groups. For persons over 65 years of age, other eligibility criteria apply to persons in receipt of the Guaranteed Income Supplement (GIS).