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Auditor General of Canada

to the House of Commons

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Chapter 4

Management of Federal Drug Benefit Programs

Office of the Auditor General of Canada

The November 2004 Report of the Auditor General of Canada comprises eight chapters, Matters of Special Importance—2004, and Main Points. The main table of contents is found at the end of this publication.

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Chapter

4

Management of Federal Drug Benefit Programs

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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Management of Federal Drug Benefit Programs

Main Points

4.1 Our audit of the federal government's drug benefit programs found a lack of leadership and co-ordination in the provision of drug benefits. The six federal organizations that administer the programs approve most of the same drugs and deliver them through the same pharmacy system in Canada. However, the failure to co-ordinate their efforts has led to missed opportunities to save money and contain costs.

4.2 Studying drug use patterns, and taking appropriate action, can prevent the misuse of drugs and help ensure that clients realize the intended health outcomes of drug benefit programs. The federal government has current, highly informative data on the drug use of each of its clients; however, these data are not being systematically assessed and disseminated to health care professionals. The data provide an important source of medically relevant information for Health Canada, Veterans Affairs, the RCMP, and National Defence, all of whom share responsibility for improving or maintaining the health of their respective clientele, in partnership with industry and service providers. Failure to share this information could result in less than optimal health outcomes for many clients.

4.3 In managing these programs, federal organizations have not taken advantage of known cost-saving opportunities in order to ensure the programs' long-term sustainability. As a result, the government may be spending tens of millions of dollars annually more than necessary.

Other observations

4.4 The federal government is the fourth largest payer of prescription drug benefits in Canada, after Ontario, Quebec, and British Columbia. It spends more than $430 million annually on prescription drugs for about one million Canadians. These costs have risen by 25 percent over the past two years.

4.5 Other than for cost, most federal organizations have neither objectives nor performance measures that are specific to their drug benefit activities. Without specific objectives and related performance information, organizations have no means of assessing whether their activities are meeting intended purposes and are cost-effective.

4.6 Audits of pharmacies have identified significant overcharges owed to the Crown. These amounts owing have not been recorded in the Public Accounts of Canada as required by the Treasury Board Policy on Receivables Management.

The government has responded. Federal organizations agree with all of our recommendations and their responses are included in this chapter. The government has told us that details on actions to be taken will be communicated to us within a few months.

Introduction

4.7 The use of pharmaceutical drug products is a fact of life for many Canadians. These products prevent and cure diseases, help to manage chronic medical conditions, and provide relief from many regular aches and pains. Over the past 40 years, drug products have fundamentally changed the face of health care in Canada and will continue to play a prominent role in the years to come.

4.8 The manufacture, distribution, and sale of drug products form a multi-billion-dollar industry in Canada. In 2003, an estimated $19.6 billion was spent on them—the second largest component of all health care spending in Canada, after hospital expenditures.

4.9 Pharmaceuticals are not insured under the *Canada Health Act*, except for drugs dispensed in facilities providing hospital care. While many Canadians must pay for their prescription drugs themselves, some are covered by private or corporate drug benefit plans or by provincial or federal government programs.

4.10 About one million Canadians are eligible for federal drug benefits. The programs providing the benefits have been among the fastest-growing areas of federal spending on health. Between 2000–01 and 2002–03, spending on these programs grew from $350 million to $438 million, a 25 percent increase in just two years. The federal government is now the fourth largest payer of drug benefits in Canada, after Ontario, Quebec, and British Columbia.

4.11 Collectively, provincial governments are estimated to provide benefits to over nine million Canadians. We conducted this audit in co-operation with provincial auditors general, most of whom plan to report the results of their audits to their respective provincial legislatures in the coming months.

Focus of the audit

4.12 This audit examined the drug benefit programs of six federal organizations: Health Canada (benefits for First Nations and Inuit), Veterans Affairs Canada (veterans), National Defence (Canadian Forces members), the Royal Canadian Mounted Police (members), Citizenship and Immigration Canada (certain designated classes of migrants), and Correctional Service Canada (inmates of federal penitentiaries and some former inmates on parole).

4.13 Although our audit work included following up on audits completed between 1996 and 2000 in Health Canada and Veterans Affairs Canada, most of our work focussed on more recent activities. A summary of our follow-up conclusions is in the Appendix. More details on the objectives, scope, approach, and criteria are included in **About the Audit** at the end of the chapter.

Observations and Recommendations

Program features

4.14 There are important distinctions among the six federal programs. Citizenship and Immigration Canada, for example, provides drug benefits to clients for a relatively short period, averaging one and a half years, and this clientele varies significantly throughout the year. In contrast, Health Canada provides drug benefits to its clients throughout their lives. The relationship of organizations to clients also differs significantly, from provision of basic medical services by Correctional Service Canada during clients' confinement to provision of long-term care and living assistance by Veterans Affairs Canada. National Defence and the RCMP provide drug benefits, in part, to ensure operational effectiveness. The costs of providing such drug benefits in 2002–03 ranged from $5 million at Citizenship and Immigration Canada to $290 million at Health Canada. Exhibit 4.1 summarizes the size of each program. Although the drug benefit programs are as different as the mandates of the six federal organizations we audited, they approve many of the same drug products and are similar in several respects (Exhibit 4.2).

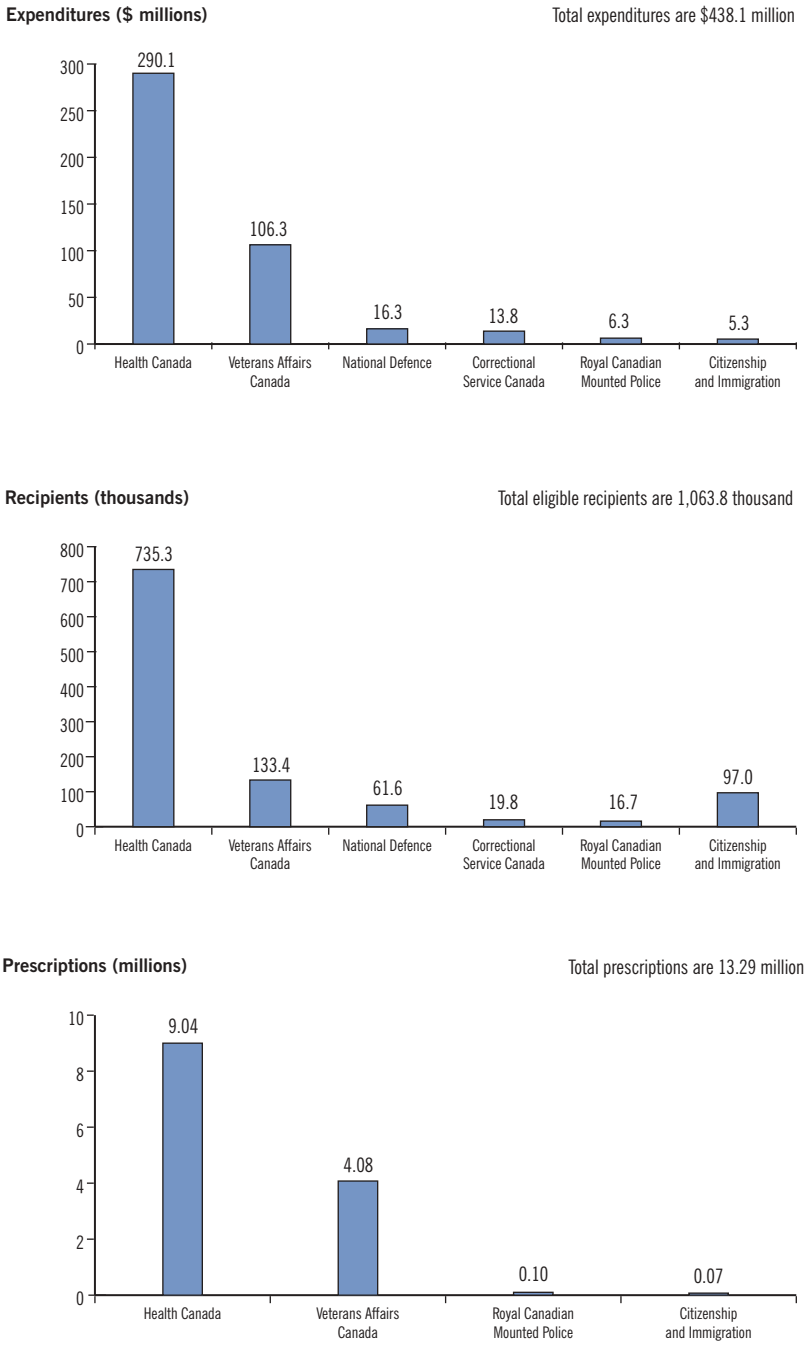
Drug benefit process involves several parties

4.15 Federal organizations are not alone in delivering these services. They must work with other stakeholders, including doctors, pharmacists, provincial governments, and claims administrators under contract to the government. Doctors have an important responsibility for patient care and are normally paid a professional fee by provincial governments for any medical assessment associated with the prescription of a drug. Pharmacists are normally responsible for dispensing drugs, while both doctors and pharmacists are responsible for ensuring that different drugs prescribed to patients (sometimes by different doctors) do not interact in a negative way. Pharmacists also play vital roles in counselling patients and recording information on the various drugs prescribed to a patient, including information provided by the patient or the prescribing doctor. Pharmacists bill the respective federal drug programs for the prescriptions they fill, including the costs of the drugs and their professional dispensing fee. A claims administrator under contract with the federal government usually makes the actual payment and is reimbursed for its costs as well as a service fee for each transaction. Patients also play a role in their own health care.

Objectives, performance measures, and reporting

4.16 Program objectives state the purpose or benefits of an organization's activities. Performance measures provide information about the program's progress toward each objective, and their use can help to inform management and other decision makers when corrective action is needed. Our Office and the Treasury Board Secretariat have long emphasized the importance of setting clear program objectives and measuring performance toward achieving them. Without objectives and performance measures, it is often difficult to determine the most effective strategies for achieving results.

Exhibit 4.1 Size and cost of drug benefit programs, 2002–03



Consequently, program managers may fund activities that are ineffective and not necessarily meeting the needs of their clients.

4.17 Given the size and costs of the federal drug benefit programs, we expected that each program would have clearly stated objectives and

Exhibit 4.2 Similarities of the six federal drug benefit programs

- Most programs have the goal of optimizing the health status of its clients.
- Most program clients obtain prescriptions from their doctors and drugs from pharmacies.
- The programs' clients typically do not pay for their drugs; the federal government reimburses the pharmacies.
- Program costs for providing drug benefits have increased significantly in recent years.
- Most programs use third-party claims administrators to manage payment of benefits.
- Programs provide benefits for many of the same drug products.
- Most programs keep detailed information on their client transactions.

performance measures. We also expected that objectives would focus on improved outcomes, reflecting the positive therapeutic effects of drugs and the value that taxpayers are obtaining for their tax dollars. Finally, we expected that performance information would be reported to Parliament.

4.18 **Drug benefit programs are part of larger programs.** In all cases, we found that the provision of drug benefits is a component of larger health care programs, each with its own set of general health objectives. Therefore, we asked each of the six federal organizations to provide us with the drug benefit objectives and performance measures being used in the assessment of their larger programs. We also reviewed internal documents that we expected would include such measures and performance reporting where warranted.

4.19 We found that the objectives for the organizations' health-related programs do not include objectives specific to drug benefits in most cases. Health Canada, National Defence, and Citizenship and Immigration Canada had objectives specific to the costs of their drug benefit activities. Although the RCMP, National Defence, and Health Canada have program objectives for their larger programs for which the monitoring of drug use could serve as a performance measure, only National Defence has analyzed its data for such purposes. For example, National Defence has performance measures to track objectives related to operational readiness and, in fact, it routinely collects and analyzes data related to the availability of essential medication and its provision to personnel in operational settings.

Decision making is not based on performance data

4.20 Collective or individual objectives and associated performance measures for providing drug benefits are necessary in order for management to assess whether their related activities are meeting their intended purposes and are cost-effective. They are also needed to assess how the provision of drugs contributes to achieving their broader program objectives. However, most organizations do not have the information they need for decision making or for reporting on the progress of their drug benefit activities toward their planned outcomes. In particular, management should be able to decide

which drugs are to be maintained, added, or deleted from their drug list. This decision should be based on their own performance information such as actual cost-benefit data. However, other than National Defence, organizations do not regularly analyze such information for this purpose.

4.21 **Recommendation.** Health Canada, Veterans Affairs Canada, National Defence, the RCMP, Citizenship and Immigration Canada, and Correctional Service Canada should, either collectively or individually, establish or strengthen objectives and performance measures for their drug benefit activities and report to Parliament as appropriate.

Organizations' response: Agreed. Federal organizations will establish or strengthen drug benefit program objectives and performance measures appropriate to their client populations and mandate. All actions will support the National Pharmaceutical Strategy commitments made by First Ministers. Departments will report regularly on progress.

Analyzing drug use trends

Claims processing databases provide valuable information

4.22 Analyzing how drugs are being used is critical in supporting the provision of good health care. Studying drug use patterns and taking appropriate action to prevent the misuse of drugs can help ensure the intended health outcomes of drug benefit programs. Five federal organizations capture all individual client transactions on databases. These databases may constitute a unique source of information on about one million Canadians and 13 million individual drug transactions per year, including the names and quantities of drugs prescribed, the respective dates, and associated costs. Experts from government, academia, and U.S. pharmacare consider the analysis of this information to be an important element in the management of pharmacare programs and believe that such analysis can have a significant impact on the quality of health care. These databases are important sources of medically relevant information for Health Canada, Veterans Affairs Canada, the RCMP, and National Defence, all of whom share responsibility for improving or maintaining the health of their respective clientele, in partnership with doctors and pharmacists.

- **Health Canada.** In its 2002–03 Annual Report on the Non-Insured Health Benefits Program, Health Canada states, "The purpose of the program is to provide non-insured health benefits to First Nations and Inuit people in a manner that contributes to the achievement of an overall health status for First Nations and Inuit that is comparable to that of the Canadian population as a whole."
- **Veterans Affairs Canada.** The Veterans Affairs Canada Adverse Drug Utilization Review Policy states, "The focus of Utilization Review is to ensure that appropriate health care is received by members and rendered by physicians and pharmacists. This is achieved by assessing whether benefits received under the program result in optimum health outcomes for members. Medical and health-based analyses are performed with the focus on members' wellness. The goal is to alert

health care providers to situations of adverse benefit use by supplying them with specific details of the member's utilization patterns."

- **RCMP.** In its 1998 Strategic Plan, the RCMP indicated its commitment to medical surveillance: "Because of concern about these safety issues and, also, because of the enormous potential liability that would result from failure to apply due diligence to prevent resultant damage to life or property, the Force has a legal and ethical duty to ensure that members are fit to safely perform the tasks of police work."

- **National Defence.** National Defence has two relevant objectives for analyzing drug use: to enable the provision of patient care through judicious use of medicines; and to administer a drug program based on four principles—operational readiness, fairness, equality, and health outcomes.

4.23 Given this policy orientation, we expected these four organizations to routinely conduct analyses of drug use and communicate all relevant information to health care decision makers to assist them in optimizing the health care outcomes of their respective clients.

4.24 Correctional Service Canada and Citizenship and Immigration Canada have limited programs that provide only basic health care services and, as such, we did not expect substantial analyses of their drug use databases.

4.25 The data from the claims processing databases can be used for two types of drug use analyses: concurrent analyses and retrospective analyses. Concurrent analyses identify potential sources of therapeutic problems at the time prescriptions are dispensed. In this regard, alert fields can be programmed into the systems that advise pharmacists if filling a prescription could put a patient's health at risk (for example, when two drugs may react negatively with each other). Retrospective analyses examine drug use patterns over defined periods for individual clients and groups of clients considered at risk.

4.26 **Concurrent analyses.** As the claims processing databases constitute the only comprehensive source of data on drug use for many clients, this information is very important to health care decision makers. Access to these data is especially crucial for certain client groups, such as the more than 166,000 seniors and thousands of diabetics served by federal drug benefit programs.

4.27 In our 1997 audit, Chapter 13, First Nations Health, and in our 2000 follow-up, we reported that clients were accessing large numbers of prescription drugs. In 1997 we recommended that Health Canada's automated system alert pharmacists to potentially inappropriate drug use in order to facilitate timely intervention. We also expected that organizations with a large number of senior citizen clients, such as Veterans Affairs Canada, would routinely analyze their data for drug use patterns that are known to put senior citizens at risk.

Claims processing systems do not detect many types of potential abuse

4.28 Health Canada's system provides pharmacy alerts for duplicate drug therapy and drug-to-drug interactions. This information is routinely captured in the Department's claims processing database. Pharmacists can choose to override these alerts after they have consulted with a doctor, the patient, or other sources and are satisfied with the explanation.

4.29 In our 2000 audit of Health Canada's drug benefit program, we recommended that the program more closely monitor pharmacists' overrides of warning messages for drug use and undertake rigorous and ongoing analysis to assess the effectiveness of the messages. The Department took appropriate action and reported the analysis of pharmacy overrides and action taken.

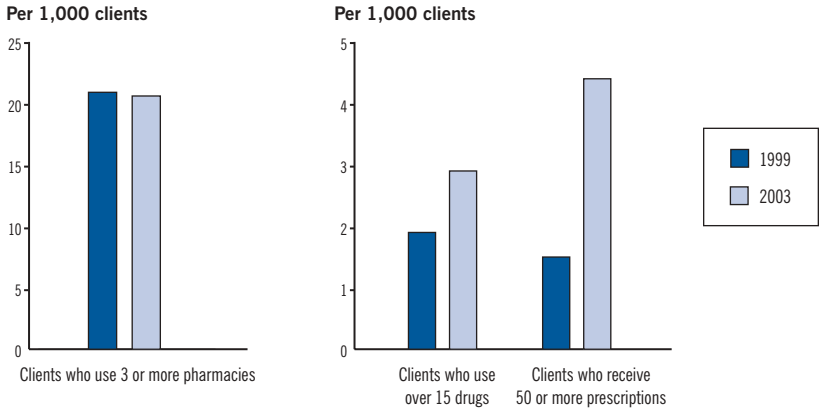
4.30 In 2002–03, the Department's claims processing system rejected about 300,000 claims of the more than nine million drug transactions. Of these rejections, 83,000 (28 percent) were overridden and paid by the program. About 70 percent of the overridden claims were for duplicate prescriptions claimed in the same pharmacy; 43 percent of these were based on the client providing an adequate explanation to the pharmacist before the prescription was filled. This system is now used to assist Health Canada in identifying pharmacies for audit.

4.31 Veterans Affairs Canada set up a claims processing system in 1997–98 that also identifies duplicate drug therapy and drug-to-drug interactions at the time of dispensing. Unlike Health Canada's system though, it also identifies cases where multiple narcotics are being dispensed for the same client. However, it issues an alert only for drugs that have been previously dispensed from another pharmacy. It does not issue alerts for intrapharmacy claims; these are left to the discretion of the pharmacist. Thus, Veterans Affairs Canada does not collect override data for duplicate prescriptions claimed by the same pharmacy. Nor does the Department collate information on claims processing alerts or assess the volume of alerts and overrides, and the reasons for the overrides.

4.32 Citizenship and Immigration Canada does not yet have an automated alert system and does not collect override information as its automated system is still being developed. Correctional Service Canada and National Defence do not maintain alert and override systems for internal operations, given the highly controlled nature of their operations.

4.33 **Health Canada and Veterans Affairs Canada clients access large numbers of prescription drugs.** In our 1997 Report, Chapter 13, Health Canada—First Nations Health, and the follow-up in 2000, we identified potential abuse by clients from the over-prescribing of drugs. We repeated this analysis in this audit. As shown in Exhibit 4.3, we found that the number of clients accessing 50 or more prescriptions had increased significantly compared with the number we observed in our 2000 audit (corrected for population growth). Health Canada was unable to explain why the number of such clients had almost tripled in four years.

Exhibit 4.3 **Health Canada—Key indicators of excess prescription drug use***



*Based on data for period July to September 1999 and 2003

4.34 In its 2001 report pertaining to our 2000 audit, the Public Accounts Committee recommended that Health Canada immediately upgrade its system to provide pharmacists with the names and quantities of drugs prescribed and the respective dates for at least a client's last three prescriptions, as well as relevant details on the doctor visited. As noted in the Appendix, this recommendation has not been implemented.

4.35 We also analyzed departmental data for July–September of 2003 for four of the six federal organizations we examined (Exhibit 4.4). The data showed that a considerable number of Veterans Affairs Canada and Health Canada clients were taking more than 15 different drugs during this 90-day period and that a significant number had received 50 or more prescriptions during the period. We found that both departments' claims processing systems do not send alerts to identify clients accessing large numbers of drugs.

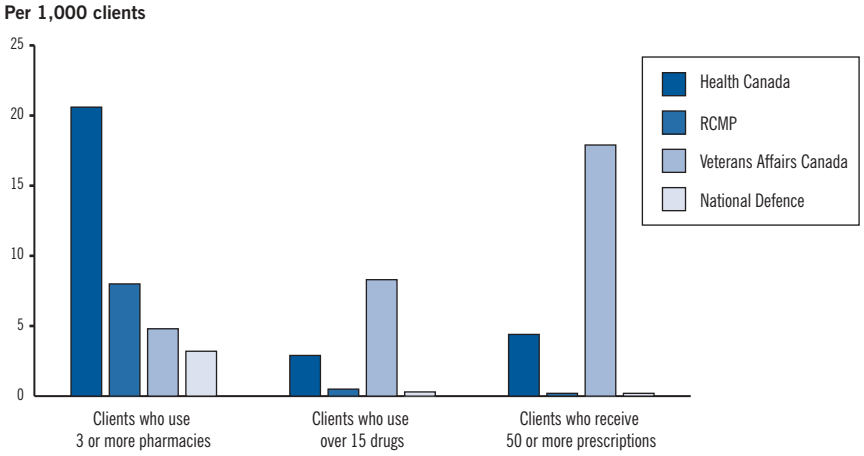
Narcotics—A class of drugs that are normally opium derivatives but also includes restricted drugs such as cocaine and marijuana. For the purpose of this audit, the term "narcotics" refers only to opioid narcotics such as morphine, codeine, and oxycodone, which are used to relieve pain. Excessive dosage of these drugs may cause unconsciousness, coma, and even death. Repeated use may cause physical dependency and, in certain individuals, addiction.

4.36 **Clients obtaining multiple narcotics.** Narcotics have a high potential for misuse. As such, we expected the organizations' claims processing systems to be more sensitive to the potential for misuse and provide pharmacists with immediate alerts for unusual opioid narcotic prescription patterns that suggest the need for further investigation.

4.37 To determine if the systems discourage the abuse of such drugs, we identified clients obtaining multiple narcotics using prescriptions from multiple doctors through multiple pharmacies. Experts in this field consider that clients acquiring two or more different narcotics through a combination of two or three doctors and two or three pharmacies should be considered at risk for drug misuse; clients with combinations of 11 or more doctors and 11 or more pharmacies in a year should be considered at high risk for problematic use of such medications, including misuse and addiction.

4.38 We found that in 2002–03 over 900 clients from the four programs analyzed were on two or more different narcotics simultaneously and had

Exhibit 4.4 Organizational comparison—Key indicators of excess prescription drug use*



*Based on data for period July to September 2003

acquired these drugs through prescriptions from two or more doctors and two or more pharmacies. Health Canada had 128 medium- and 94 high-risk clients receiving multiple narcotics simultaneously through a combination of seven or more doctors and seven or more pharmacies (Exhibit 4.5). While some cases may be attributable to terminally ill patients receiving end-of-life care, many patterns were highly suggestive of problematic use, such as drug misuse, addiction, and possibly trade or sale. For example, we identified a number of Health Canada clients who were dispensed large quantities of four or more different narcotics through up to 46 different combinations of doctors and pharmacies; one client was able to regularly acquire large quantities of seven different narcotics through 29 different doctors and 21 different pharmacies in one year (974 tablets each containing 30mg of codeine were obtained for three of these narcotics in one month). We also analyzed the use of benzodiazepines and found similar results. We found that Veterans Affairs Canada's claims processing system provides immediate alerts to pharmacists for the use of multiple narcotics and for the use of multiple benzodiazepines. Heath Canada's system does neither.

Benzodiazepines—So-called "minor" tranquilizers and depressants that relieve anxiety and produce sleep. In certain individuals, they can lead to addiction if taken for an extended period of time. Adverse effects include confusion, drowsiness, hallucinations, mental depression, and impaired co-ordination.

4.39 We also examined the concurrent use of methadone and other opioid narcotics by Health Canada clients to further test the Department's claims processing alert system. Expert advice received from the Centre for Addiction and Mental Health indicates that under appropriate professional supervision, methadone can be used (though not exclusively) to treat drug addictions involving opioid narcotics, such as heroin, morphine, and hydromorphine. In such cases, however, the concurrent use of methadone and other opioid narcotics is normally discouraged. Furthermore, a methadone maintenance program is intended to be a highly structured treatment model that requires careful oversight and close monitoring by both doctors and pharmacists in order to safely treat a complex group of patients with a minimum of risk to the patients and public.

Methadone—A long-lasting synthetic opioid used to treat pain and/or opioid addiction. In some cases, methadone can be effectively used to treat both conditions.

Exhibit 4.5 **Risk levels for clients using opioid narcotics (excluding methadone), 2002–03**

Organization	Number of clients at specific risk levels			
	Minimum	Low	Medium	High
Health Canada	45	135	128	94
Veterans Affairs Canada	446	39	6	1
RCMP	57	8	0	0
National Defence*	12	1	0	0

*2003–04

Risks for clients obtaining two or more narcotics:

Minimum—two or three doctors and two or three pharmacies
Low—four to six doctors and four to six pharmacies
Medium—seven to ten doctors and seven to ten pharmacies
High—over ten doctors and over ten pharmacies

4.40 Expert advice also points out that methadone is an unusual drug in terms of regulations surrounding its use. It is unique in that while it is particularly effective for the treatment of opioid addiction, it is also very effective for pain management. In many countries, including Canada, methadone use for the treatment of opioid narcotic addiction is highly regulated and requires a special federal permit (exemption) that is typically given only after advanced training by the prescribing physician. When methadone is used to treat pain, the permit does not require additional formal training. Likewise, there are currently no specific guidelines in place to assist prescribers in the ways to safely use methadone for the treatment of pain. As a result, it is possible for patients who would benefit from the highly structured and supportive care offered by methadone maintenance treatment programs to treat opioid addiction to seek treatment through less structured pain management programs. When methadone is used to treat two different and sometimes co-occurring conditions under two completely different regulatory models, the need to closely monitor its use becomes even more important since the risk of misuse is significant.

"In cases where clients are obtaining multiple controlled substances from different doctors, the likelihood of each prescriber being aware of the prescriptions for controlled substances by the other practitioners is reduced and decreases as the number of prescribers increases."

Dr. Douglas Gourlay, MD, MSc, FRCPC, FASAM
Centre for Addiction and Mental Health
Wasser Pain Management Centre, Mount Sinai Hospital

4.41 Therefore, we expected Health Canada's system to identify and flag for pharmacists the dispensing of opioid narcotics to clients who were also receiving regular methadone treatment for opioid narcotic addiction, particularly when prescribed by different doctors and subsequently dispensed by different pharmacists.

4.42 In 2002–03, Health Canada had 1,253 clients using methadone; 967 were in a methadone program for at least 60 consecutive days and, of these clients, 299 were concurrently prescribed one or more opioid narcotics. We found that more than 70 percent of these 299 clients had different doctors prescribe either opioids or methadone and 52 percent used a different pharmacy for each drug. Clients, who receive opioid narcotics from doctors other than those who prescribed methadone, especially without the

methadone prescriber's knowledge, can be considered at high risk for drug misuse and, ultimately, program failure. Health Canada's claims processing system does not provide pharmacists with alerts when dispensing opioid narcotics to clients also receiving methadone. If such clients were identified early through effective alert systems, appropriate interventions could be initiated and treatment outcomes improved.

Programs are data-rich but information-poor

4.43 **Retrospective analyses.** The claims processing databases offer a wealth of information that can provide valuable insights into health trends of clients, the success of specific program efforts, and, to some extent, the appropriateness of drug benefits provided to clients. As a minimum, we expected organizations with large programs to conduct routine systematic analyses of these databases, both to evaluate the overall effectiveness of their programs and to improve the health outcomes for their clients.

4.44 We found that these large organizations do not use the substantial information in their database to consistently and systematically look for patterns of inappropriate use. Though not comprehensive, Veterans Affairs Canada's retrospective drug utilization review does target methadone use, monthly codeine use, the top 20 users of over-the-counter drugs, and the top 20 users of prescription drugs. When an extreme case of adverse use is identified, the Department's policy is to send letters to doctors and pharmacists and to mobilize a district health care team. The team consists of a medical officer, nurse, counsellors, and whatever outside expertise and resources are needed to assist the client, including drug addiction services and pain management clinics. The Department's drug use policy manual states that a "signed consent form is not necessary prior to sending provider notifications as this process is viewed as a service performed in the member's best interest and to protect their health." While this manual also states that Veterans Affairs Canada is to review historical information such as drug-to-drug interactions, the Department does not systematically conduct comprehensive risk analyses of this nature to determine patterns of inappropriate drug use; nor is such information communicated to health care professionals.

4.45 Other organizations conduct limited drug use analysis. Effective 2004, National Defence introduced a system to capture all pharmaceutical information pertaining to transactions both on- and off-base. Prior to this, its efforts were limited to reviewing adverse drug events identified in the literature and case reports on individual adverse reactions. These reviews led to a number of in-depth studies to evaluate specific drug use issues and often led to changes in drug use policies. The RCMP conducts drug utilization review for a small set of drugs that would potentially threaten the operational readiness of members, including psychoactive drugs, cardiac drugs, anti-convulsant drugs, and insulin.

4.46 In previous audits reported in 1997 and again in 2000, we recommended that Health Canada identify significant patterns of inappropriate use of prescription drugs and follow up with doctors,

pharmacists, and professional bodies. We noted in our audit in 2000 that Health Canada had begun to conduct drug use analysis and that the Department had shown a decline in the number of cases involving access to large amounts of central nervous system drugs. This intervention was stopped in 1999. Health Canada stated in response to our 2000 audit that once consent was obtained, drug utilization review would be fully reinstated. It made similar commitments to the Public Accounts Committee in 2001.

4.47 Health Canada informed us that, by the end of our audit, it had obtained consent from over 174,000 of its clients, about one quarter of all eligible recipients. Nevertheless, it still had not reinstated drug utilization review for these clients. Furthermore, the Department could have conducted retrospective analyses of clients for whom consent had not been provided by replacing names with a code that would have effectively anonymized the data. This would have at least enhanced the Department's capacity to initiate evidence-based program interventions supporting health promotion and education efforts. The Department has not conducted such analyses. In December 2003, it established the Drug Use Evaluation Advisory Committee, with terms of reference finalized in June 2004, in order to develop and recommend a comprehensive program to promote safe, effective, and efficient use of drugs.

"An analysis of the use of anti-platelet therapies in diabetic patients over the age of 55 years, and in particular those using nitrates, demonstrates that there is sub-optimal use of a treatment that can prevent cardiovascular events in individuals at high risk."

Mitchell Levine, MD, MSc, FRCPC
Director, Centre for Evaluation of Medicines
Professor, Department of Clinical Epidemiology and Biostatistics,
Department of Medicine,
McMaster University

4.48 To examine the potential benefit that retrospective drug utilization review could offer health care professionals, we conducted a series of retrospective anonymized analyses, using departmental databases, in areas where the standard of care is well known.

4.49 Diabetics, for example, have a two- to four-fold greater risk of experiencing a life-threatening cardiovascular event, such as a heart attack, compared with an individual without diabetes. Medical experts indicate that diabetics, particularly those over 30, would derive considerable benefit from being placed on anti-platelet drugs, such as acetylsalicylic acid (ASA) to reduce their risk of heart attack. Medical literature and experts also indicate that diabetics over 55 years of age who have also been diagnosed with heart disease have an even greater risk of heart attack, and thus the need for anti-platelet drugs is increased.

4.50 Our analysis of Health Canada's 2002–03 database identified 14,519 First Nations and Inuit clients who were 55 years or older and being treated for diabetes. More than 7,000 of these clients were not taking anti-platelet drugs. About 2,500 of these diabetics were also on drugs (nitrates) prescribed for heart disease, and over 600 of these clients were not taking an anti-platelet drug. If such information had been identified and subsequently communicated to health care professionals, it may have assisted them in the medical management of at least some clients in this population at risk. Health Canada has since completed a review of priorities for drug use analysis and in fall 2004 plans to communicate with medical and pharmacy professionals about the clinical value of diabetics taking ASA antiplatelet therapy. Such analysis does not require client consent.

4.51 **Attention to seniors is needed.** The need for therapeutic vigilance is vital for seniors if their health care outcomes are to be optimized. The drug benefit programs of Veterans Affairs Canada and Health Canada supported over 166,000 seniors in 2002–03. Many depend on a large number of drugs to maintain their health status and quality of life. However, as the number of concurrent prescriptions taken by a senior increases, so does the potential for adverse drug interactions and reactions. Certain drugs also pose a potential health risk as they are contraindicated for seniors.

4.52 In 2003, the American Medical Association revalidated a list of drugs that were considered to pose a threat to senior citizens. Using a system referred to as Beers Criteria, it assessed the drugs as low- or high-risk for patients 65 years of age and older. We expected organizations with significant numbers of elderly clients to be monitoring the prevalence of these drugs being dispensed to their senior clientele.

4.53 We limited our analysis to the prevalence of high-risk drug use within this age group in the programs of Veterans Affairs Canada and Health Canada. In 2002–03, the two departments collectively had 19,700 senior clients who were dispensed one or more such drugs. Furthermore, we found that 8,945 seniors had been prescribed two or more high-risk drugs concurrently. As shown in Exhibit 4.6, 109 seniors were taking two or more high-risk drugs concurrently that were prescribed by four or more doctors and dispensed by four or more pharmacies. Of these, 44 seniors were taking four or more high-risk drugs.

Exhibit 4.6 **Seniors receiving two or more high-risk drugs***

Number of doctors	Number of pharmacies				Total
	1	2	3	4 or more	
1	4,675	338	17	4	5,034
2	1,847	735	84	7	2,673
3	361	252	77	11	701
4 or more	180	147	101	109	537
Total	7,063	1,472	279	131	8,945

*Drugs classified as high-risk using the Beers Criteria

4.54 To mitigate the potential risk to patients, doctors need to know the entire drug use profile of a patient, particularly if it involves multiple high-risk drugs. As this is not always possible, multiple high-risk drugs prescribed by multiple doctors and dispensed by multiple pharmacies that may not have their databases linked have potentially serious implications for elderly patients. Neither of the departments' systems produces alerts for these drugs.

4.55 We also looked at the number of different drugs that senior clients of Veterans Affairs Canada and Health Canada had been prescribed for

"The common use of potentially inappropriate drugs should serve as a reminder to monitor their [patients'] drug use closely. Pharmaceutical claims databases can be important tools for accomplishing this task . . . "

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concurrent use in 2002–03. The medical literature indicates that the risk of serious adverse drug reactions in patients over the age of 65 increases along with the number of concurrent medications. Some experts consider that when the number of drugs exceeds seven, the risk of serious drug reactions approaches 100 percent. Even so, many senior citizens need to take multiple drugs simultaneously as the benefit of these medications exceeds their potential risk. However, experts suggest that these patients should be assessed by doctors regularly for adverse drug interactions and reactions. Thus, access to information contained in the claims processing databases becomes vital.

4.56 In 2002–03, almost 4,000 senior clients of Veterans Affairs Canada and Health Canada were prescribed 10 or more drugs simultaneously for 3 to 12 months (1,975 seniors over 80 years of age were on 10 or more drugs.) We selected a representative sample of 332 individuals from this population and had their drug use profiles assessed through a computer-based model for potentially harmful drug interactions. The assessment identified 1,278 potential problems of varying levels of severity. According to the assessment, 60 percent of these clients had drug use profiles that normally should be avoided but may be necessary depending on individual clinical circumstances; 28 percent of clients had drug use profiles that needed adjustment in order to avoid potential problems.

"Patients who receive multiple medications concurrently are at increased risk for drug interactions and adverse effects."

Mitchell Levine, MD, MSc, FRCPC
Department of Medicine, McMaster University

4.57 The results of this assessment were subsequently reviewed by independent medical experts. Although many of these drug interactions were considered minor in nature or difficult to assess given the lack of clinical information, some were considered sufficiently serious to warrant medical review. In many provinces, comprehensive drug use information is not always available to the doctor or pharmacist. Pharmacy databases are not always interconnected and thus the complete drug use profile of an individual needing a new prescription may not be available. The federal claims processing databases constitute the only comprehensive source of data on drug use for many clients, but this information is rarely made available to health care decision makers.

4.58 **Recommendation.** As a minimum, Veterans Affairs Canada, Health Canada, National Defence, and the RCMP should upgrade their existing claims processing systems, as necessary, to ensure that each system

- monitors pharmacists' overrides of warning messages for drug use,
- includes an alert notification when clients access large numbers of prescription drugs, and
- includes an alert notification for potential misuse of narcotics and benzodiazepines.

Organizations' response. Health Canada, Veterans Affairs, National Defence, and the RCMP agree with this recommendation. Work is underway to implement these changes, where required. Implementation may be limited by third-party point-of-sale software as well as security and privacy issues. In the longer term, the accelerated development of electronic health records and electronic prescribing practices, as per the National Pharmaceutical

Strategy commitments of First Ministers, will provide additional tools to address the specific concerns of the Auditor General.

4.59 **Recommendation.** Veterans Affairs Canada, Health Canada, National Defence, and the RCMP should begin to systematically analyze their claims processing databases for high-risk patterns of drug use, including those of narcotics and benzodiazepines. This is particularly important for high-risk groups such as senior citizens. These organizations should seek to use these analyses for

- communicating drug use information, as appropriate, to health care providers; and
- providing client-specific, retrospective information on drug use to pharmacists and doctors to assist them in achieving the best possible health care outcomes, while ensuring that client privacy is appropriately respected.

Organizations' response. Agreed. Most federal organizations have been involved in drug utilization evaluation to various degrees prior to this report and have successfully used it to identify areas of concern. The organizations will conduct more systematic analyses and co-ordinate efforts to identify high-risk patterns of drug use and communicate this information to health care professionals as appropriate. Privacy and security are significant issues that will need to be addressed. When implemented, electronic health records and electronic prescribing practices, as per the National Pharmaceutical Strategy commitments of First Ministers, will provide further tools to identify high-risk patterns of drug use and communicate information to health care professionals.

Controlling costs and managing the programs

4.60 The cost of providing drug benefits is influenced by a number of factors—some clearly not within the organizations' control, such as growth in the size of eligible populations; aging clientele; and the introduction of new, more costly drugs into the marketplace. However, organizations can influence some factors that have a significant impact on costs, and these factors must be managed. We looked at how organizations were managing several critical factors, including the following:

Formulary—A specified list of drugs authorized for use within each drug program and, in some cases, specifying the drug benefit status.

Benefit status—The designation assigned to prescription drugs: that is, full benefit, limited benefit, or no benefit. Full-benefit drugs are automatically approved when prescribed, limited-benefit drugs are approved only under certain criteria, and no-benefit drugs are generally not approved.

- **Drug products that federal organizations choose to cover**. Determining which drug products are put on a formulary and their benefit status are key determinants of program costs. Each formulary constitutes the basis for all drug payments made by an organization.
- **The use of strategies for containing costs.** Some drugs that provide the same therapeutic benefit vary significantly in price. A number of options to contain prices are available to federal programs to minimize costs without jeopardizing the quality of care provided to clients.
- **Appropriate controls for contractor systems**. Five of the six federal organizations deliver their programs through claims processing systems run by contractors. Ensuring that contractors have adequate controls in place to verify the eligibility of clients and that only appropriate, approved benefits are paid is important to avoid unapproved costs to the program.

- **Appropriate controls for pharmacy payments**. Pharmacies are the recipients of much of the federal spending on these programs. Ensuring that pharmacists follow appropriate practices for billing federal programs is key to managing costs.

Drug benefit approvals differ by program

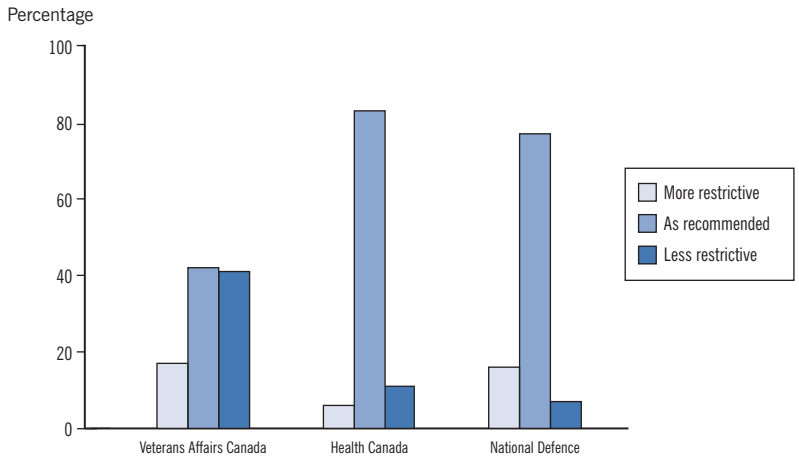
4.61 Each federal organization manages its own drug benefit formulary. For Veterans Affairs Canada, Health Canada, National Defence, and the RCMP, this includes both prescription and over-the-counter drugs. Citizenship and Immigration Canada has its own formulary and does not include many over-the-counter products. Correctional Service Canada operates five separate formularies, one for each of its operational regions.

4.62 **Federal committee for assessing new drugs has limited influence.** One of the key challenges for all of these organizations is determining which drugs to include on their formularies; each organization has autonomy in this complex process. In 1999, the federal government established the Federal Pharmaceutical and Therapeutics (P&T) Committee to provide all organizations with evidence-based advice on new drugs being considered for inclusion on federal drug formularies. The intent was to avoid duplication of effort and assure a consistent and equitable approach to providing drug benefits. Since its inception, this committee has assessed over 200 drugs newly introduced to the Canadian market. It has advised federal drug benefit programs on the relative therapeutic merits of new drugs and recommended the benefit status based on clinical evidence. In March 2002, the Common Drug Review Directorate of the Canadian Coordinating Office of Health Technology Assessment was established, and in September 2003 it became responsible for assessing new chemical entities and new combination drug products.

4.63 We expected that organizations' decisions on the benefit status of new drugs would closely mirror the recommendations of the P&T Committee. The benefit status determines which drugs are included on organizations' formularies and how easily they are obtained. Therefore, we expected that organizations would have similar formularies, at least for those drugs approved since 1999.

4.64 To assess how organizations followed the advice of the P&T Committee, we examined the over 200 drugs it had reviewed. Health Canada, National Defence, and Veterans Affairs Canada were active members of the P&T Committee, and thus we expected consistency between these programs. We found that Health Canada and National Defence had accepted the majority of the committee's recommendations and had not augmented their formularies with drugs not considered by the committee. Veterans Affairs Canada, however, listed 41 percent of the drugs reviewed by the committee in a less restrictive fashion than recommended (Exhibit 4.7). From 1999 to 2003, the Department also added at least 18 new drugs to its formulary that the Committee had not reviewed.

Exhibit 4.7 Consistency with recommendations made by the Federal Pharmaceutical and Therapeutics Committee



4.65 Although Correctional Service Canada, Citizenship and Immigration Canada, and the RCMP were founding members of the committee, they were not active participants in the committee's assessment process. Citizenship and Immigration Canada's formulary includes just over half of the drugs recommended by the P&T Committee as full-benefit drugs since 1999; the remainder of the drugs are made available by exception only.

4.66 **Provision of drug benefits is inconsistent.** We found that Health Canada relied on the evidence-based advice of the P&T Committee and therefore did not have its own formulary review committee. In contrast, Veterans Affairs Canada, National Defence, and Correctional Service Canada had their own formulary review committees, each comprised of program managers and advisors with varying levels of medical expertise. These committees routinely assessed the advice of the P&T Committee against broader departmental considerations; in many cases, their conclusions varied among each other and with the recommendations of the P&T Committee, without clear explanations. For example, Veterans Affairs Canada put a specific drug on its formulary as a full-benefit drug that the P&T Committee had recommended not to include. Health Canada included the same drug as a limited-benefit drug. National Defence followed the committee's advice and decided not to put it on its formulary. Citizenship and Immigration Canada also did not include the drug on its formulary, although it neither participated in the P&T Committee nor had its own formulary review committee.

4.67 It is not clear why the designation of drugs differs from one program to another. Although the prevalence of certain diseases varies among client populations, the therapeutic requirements should be the same.

Strategies for containing costs are underused

4.68 The federal government spent $438 million on drug products in 2002–03. We expected organizations to use various means of minimizing the prices they pay for drugs, including well-established cost management strategies such as large-volume purchasing, maximum allowable cost pricing, lowest-cost alternative, and reference-based pricing (Exhibit 4.8). The strategies are not mutually exclusive; many provinces use various combinations of these strategies. To assess organizations' efforts to contain costs, we conducted a number of tests and analyses using data from their drug claims databases where available. We also reviewed relevant literature, consulted experts, and reviewed some cost containment practices of other large drug benefit programs in Canada and abroad.

Exhibit 4.8 Some cost management strategies

There are a number of common strategies that organizations could use to control costs. These include the following:

- **Large-volume purchasing**—A common procurement strategy whereby unit costs drop as purchase volume increases.
- **Maximum allowable cost pricing**—A cost-saving strategy whereby the maximum allowable unit price is negotiated.
- **Lowest-cost alternative**—The least expensive of several drugs that are all chemically identical. Pharmacists are to follow provincial and territorial pharmacy legislation and policies to identify interchangeable products and to select the lowest-priced brand.
- **Reference-based pricing**—The process whereby, in a class of drugs of similar therapeutic efficacy, normally only the cost of the least expensive drug is reimbursed. If more expensive drugs in the class are used and not approved through a medical exceptions process, the reimbursement limit is the cost of the least expensive drug, with the patient paying the difference.

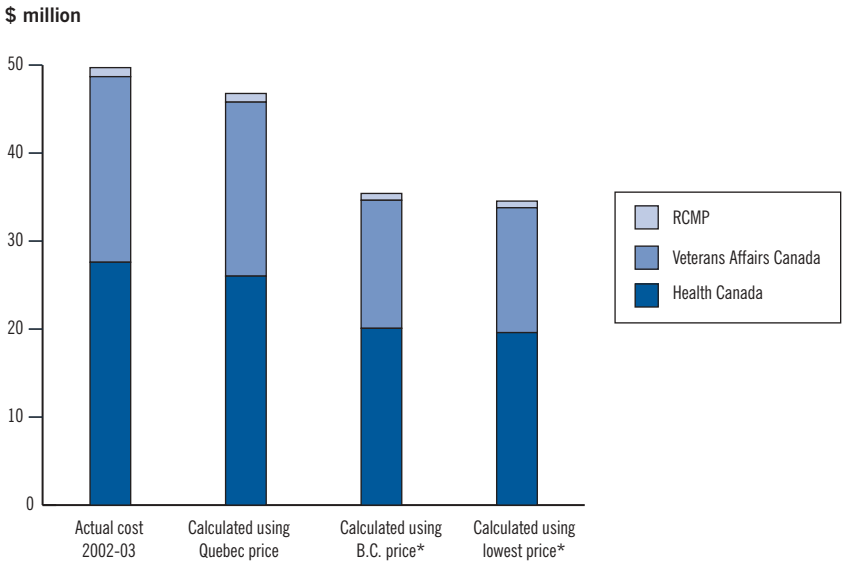
4.69 **Most federal organizations do not consistently use large-volume purchasing.** Large-scale purchasers commonly seek price reductions for large-volume purchases. We found that National Defence took advantage of negotiated drug prices for most of its purchases. Ninety percent of its drugs are dispensed on its bases. For on-base operations, the Department obtained the 500 drugs it most commonly used (and many others) at negotiated, volume-adjusted prices, and had them delivered through a wholesale distributor on a "just-in-time" basis. This amounted to significant discounts over normal wholesale prices. Correctional Service Canada also kept unit prices low by tendering, acquiring drugs through standing offers, and having its institutions classified as hospitals and pharmacies in some provinces.

4.70 The amounts paid for the same drug products vary among federal and provincial jurisdictions in Canada and even among the different federal programs. Citizenship and Immigration Canada often reimburses pharmacies at rates that reflect those of the respective provincial governments, often paying different drug prices for each province. If all federal drug benefit

programs consistently paid only the lowest amounts paid for drugs by federal and provincial programs, we believe substantial savings would be realized.

4.71 For illustration purposes, we compared the amounts paid by Veterans Affairs Canada, Health Canada, and the RCMP for the top 20 drugs used in Canada with the unit prices paid by the British Columbia and Quebec governments (Exhibit 4.9). In 2002–03 the three federal programs spent $49.7 million on these drugs (excluding dispensing fees, mark-ups, provincial co-payments, and other costs). Had their programs paid only the unit prices of the B.C. or Quebec governments, where advantageous, these programs would have saved $4 million. Had these calculations included B.C.'s reference-based prices, as discussed in paragraphs 4.75 to 4.79, the potential savings would have exceeded $15 million. These potential savings are illustrative only, as these prices have not been negotiated at a national level. However, they point to savings that may be possible through a centralized process of negotiating national drug prices. Such a strategy is consistent with recommendation 37 of the *Commission on the Future of Health Care in Canada* (R. J. Romanow, Final Report, 2002) for establishing a national drug agency that "would be responsible for leading negotiations with pharmaceutical companies and handling bulk purchase agreements in an effort to ensure that the price of prescription drugs can be contained."

Exhibit 4.9 Top 20 drugs used in Canada—Comparison of actual federal cost versus potential cost using provincial prices



*Includes British Columbia reference-based price where appropriate

4.72 In its *Final Report on the State of the Health Care System in Canada* (October 2002), the Standing Senate Committee on Social Affairs, Science and Technology also appreciated "the substantial buying power of a single national buying agency which would strengthen the ability of public

prescription drug insurance plans to negotiate the lowest possible purchase prices from drug companies." We also believe a process of centralized negotiation would offer significant opportunities for cost savings, well beyond what individual programs could achieve.

4.73 **Lowest-cost alternative strategy underused.** A lowest-cost alternative strategy would systematically remove drugs from a benefit list or restrict their use, as less expensive and equally effective alternatives become available. In this regard, some provinces and territories have already taken steps to implement policies requiring substitution of drugs with a lowest-cost alternative. These policies encourage pharmacists to substitute a therapeutically equivalent generic drug for a higher-cost brand name drug unless the latter is medically justified. If a client insists on the higher-cost drug and it is not justified, the claim is reduced to the lowest-cost alternative and the client must pay the difference.

4.74 The introduction to Health Canada's drug benefit list states that the program will reimburse only the best price for drug products in a group of interchangeable products. Pharmacists are to follow provincial and territorial pharmacy legislation and policies to identify interchangeable products and to select the lowest-priced brand. We therefore expected Health Canada and possibly other federal organizations to be reimbursing only the lowest-cost interchangeable drug products. We found that National Defence restricts the options available for many therapeutically equivalent drug products, both to contain costs and to limit the number of drugs it must deploy to operational settings. Citizenship and Immigration Canada also uses this lowest-cost alternative approach, replacing brand name drugs with generic equivalents as they become available. As such, its drug benefit list is well under half the size of the lists of Veterans Affairs Canada and the RCMP.

4.75 **Reference-based pricing not fully used.** British Columbia selectively uses reference-based pricing as another strategy to control costs. Drugs in the same class are not chemically identical but they are equivalent, as recommended by an expert advisory committee. If more expensive drugs in a class are used and not approved through a medical exceptions process, the reimbursement limit is the cost of the least expensive drug, with the patient paying the difference. Large drug benefit programs can use referenced-based pricing as a means of minimizing drug costs without compromising the quality of care.

4.76 **Test case: Drugs used to treat disorders such as stomach ulcers**. We explored the merit of reference-based pricing by examining organizations' purchases of proton pump inhibitors (PPI), a class of drugs used to treat certain disorders such as stomach ulcers. National Defence and the Province of British Columbia consider that although individual proton pump inhibitors are different chemical entities, their therapeutic effects are sufficiently similar to make them fully equivalent. In accordance with recommendations by both organizations' expert advisor committees on the drugs' therapeutic equivalence, cost determined which of the interchangeable drug products were listed on their respective drug formularies.

4.77 The cost of some proton pump inhibitors is over $2.00 per dose. In March 2001, National Defence amended its coverage for proton pump inhibitors to include only one for first-line coverage, which it obtained for $0.45 per dose. In June 2003, British Columbia amended its Pharmacare coverage for proton pump inhibitors so that first-line coverage would be paid only for the least expensive PPI product, which it obtained for $0.6955 per dose. In October 2003, Health Canada also began to take a similar approach, requiring the lowest-cost product to be used unless a more expensive drug was medically justified. At the end of our audit, Health Canada had not yet conducted an analysis to determine the extent of savings.

4.78 Federal drug programs collectively paid over $17 million for PPIs in 2002–03. To estimate the potential savings that organizations could have realized, we applied both British Columbia's and National Defence's price for the lowest-cost alternative PPI to each federal program's actual purchases for 2002–03. We found that Veterans Affairs Canada, the RCMP, and Health Canada could have collectively saved between $11 million (British Columbia pricing) and $13 million (National Defence pricing) in PPI costs in one year by requiring that their formularies cover only the lowest-cost PPI, unless medically justified (Exhibit 4.10). While these estimates are illustrative only, we believe that reference-based pricing could have offered significant savings without compromising patient care; higher-priced alternatives would have been made available if medically justified.

4.79 Although the quality of care is important, meeting the therapeutic needs of clients and achieving a cost-effective program need not be mutually exclusive. The examples of large-volume purchasing and reference-based pricing illustrate the potential for significant savings without compromising health care. We believe these do not represent the full extent of the potential for such savings. Similar opportunities have also been identified that relate to the growing use of new drugs for important treatment areas, such as for arthritis; there may be many more.

Most organizations have appropriate controls for claims processing systems

4.80 Five of the six federal programs we examined have centralized claims processing databases on drug use that are operated by claims administrators. This arrangement facilitates the processing of millions of drug claims from about 7,400 pharmacies each year. During 2003–04, claims administrators were paid $43.3 million for administrative services, including $13.2 million in transaction fees for drug claims. With hundreds of millions of dollars paid out for millions of transactions each year, we expected that organizations would have a control framework to ensure that contractors administer claims efficiently and effectively.

4.81 **Controls for claims verification are sufficient.** We examined control frameworks in each of the five organizations that use contractors as claim administrators. We expected these organizations to be able to ensure that their contractors have controls in place to verify eligibility, that drugs are matched with the drug benefit list for appropriateness and cost, and that procedures are followed for drugs requiring prior approval and special

Exhibit 4.10 **Cost containment strategies—Proton pump inhibitors (PPI)*, 2002–03 ($ thousands)**

Organization	Actual cost of PPI	Cost using National Defence price ($0.45)	Cost using British Columbia's Pharmacare price ($0.6955)	Range of possible savings
Health Canada	10,802	2,149	3,322	7,480 to 8,653
Veterans Affairs Canada	6,233	2,135	3,144	3,089 to 4,098
RCMP	470	100	154	316 to 370
Total	**$17,505**	**$4,384**	**$6,620**	**$10,885 to $13,121**

*Price comparisons for different drugs within the same class

authorization. We also expected these organizations to flag duplicate claims and ineligible drugs, and to verify the validity, completeness, and accuracy of claims submitted.

4.82 We reviewed samples of system reports designed to alert the organizations to ineligible recipients, mismatched benefits, and unapproved costs. We expected the organizations to carry out a regular review of these reports, of suspended and rejected claims, and of any anomalies.

4.83 We found that the five organizations have adequate controls in place for pre-payment verification—a process that confirms the eligibility of the client and the validity of the drug benefit before payment is approved. The organizations are able to ensure that procedures for prior approval and special authorization are followed. We also found that all of the organizations using contractors to process claims review post-payment transaction data to check accuracy and identify anomalies. We did not audit individual transactions or the claims payment systems owned and operated by the contractors.

4.84 **Veterans Affairs Canada delegates key program components.** In our examination of program delivery, we found that Veterans Affairs Canada had delegated a number of important functions to its claims administrator, including the following:

- participating and providing secretariat services for the Department's Formulary Review Committee and providing key technical advice and recommendations on proposed benefit status and on additions and deletions of drugs on the benefit list;
- playing a leading role in a departmental committee that met in 2002–03 to identify cost-saving proposals for the drug purchases;
- dealing, on behalf of the Department, with pharmacies and pharmacy associations in Atlantic Canada for dispensing fees and other matters;
- developing the plans for pharmacy audits (for departmental approval);

- serving as the primary departmental contact for industry when companies seek information on the Department's drug benefits program; and
- leading much of the Department's analysis of drug use. The contractor is also specifically referenced in Veteran Affairs Canada's Drug Utilization Review policy manual.

4.85 We are concerned about the extent to which the contractor is involved in so many important aspects of Veterans Affairs Canada's program activities. We saw no evidence that the contractor makes management decisions on behalf of the Department. Nonetheless, this delegation of program responsibilities creates significant dependence by Veterans Affairs Canada on its contractor for making informed decisions about key elements of its drug benefit program. This includes, for example, analyzing whether appropriate health care is being received by its members. We are also concerned that key technical capabilities and analytical competencies have been delegated away from the Department, which may compromise its ability to make important decisions independent of the contractor. The RCMP also relies on Veterans Affairs Canada's claims processor for drug use reports and industry representation. In contrast, National Defence has retained these functions within its organization. Health Canada and Citizenship and Immigration Canada have separate claims processors and do not rely on them to make decisions on program management.

Improved controls for pharmacy payments are needed

4.86 For most of the programs we audited, pharmacies are key partners in the delivery of prescription drug benefits to government clients. Most of Canada's pharmacies process drug claims for federal programs. Given the sheer volume of transactions and funds involved, we expected organizations to have processes in place to monitor and minimize pharmacy costs.

4.87 To assess the impact of pharmacy costs on organizations' overall drug costs and to assess opportunities for savings, we examined the fees paid to pharmacists by Health Canada's and Veterans Affairs Canada's programs. We found that in most cases each department has its own dispensing fee and mark-up schedules. Furthermore, we found that dispensing fees paid by federal programs are often higher than those paid by provincial drug benefit programs.

4.88 The Health Care Coordinating Initiative (HCCI), now the Federal Health Care Partnership, was established in 1994 to "co-ordinate federal government purchasing of health care services and products for their eligible clients at the lowest possible cost through co-ordination of effort among departments and agencies." In 1997 the HCCI negotiated a single dispensing fee schedule with the Saskatchewan Pharmacy Association on behalf of Health Canada, Veterans Affairs Canada, and the RCMP. This agreement was renewed in July 2000 for three years. The HCCI estimated the savings for these three programs at about $2 million per year and has forecast that these savings will continue through 2006–07.

4.89 In 2002–03, the federal drug benefit programs paid close to $100 million in dispensing fees and mark-ups to pharmacies, more than 20 percent of federal expenditures on drug benefits. Given the significant savings negotiated with pharmacists in Saskatchewan, we expected that similar negotiations would have occurred with other provincial pharmacy associations. This has not been the case. Participation in the Federal Health Care Partnership by federal organizations is voluntary, and the Partnership represents the federal government only when organizations choose to participate.

4.90 **Lack of management control in payment of dispensing fees.** We analyzed dispensing fee data for evidence of a practice referred to as prescription splitting. Generally, the length of time covered by a prescription is determined by the doctor. Medications for many chronic illnesses are normally prescribed for periods of one to three months. As such, we expected organizations to review and challenge pharmacists' dispensing fee charges for drugs associated with chronic illnesses and dispensed for shorter periods.

4.91 We analyzed the claims processing databases of Health Canada and Veterans Affairs Canada to identify clients who had received the same drug continuously for at least three months; this would normally reflect the use of the drug for an ongoing medical condition. For this group of clients, we found that many individuals on long-term medications were routinely being issued weekly and even daily prescriptions. Many clients were being dispensed six or seven different drugs daily, with full dispensing fees being charged to the program each day, for each drug. In one case, a client was dispensed 12 drugs on an almost daily basis. Professional fees were submitted each day for each drug, totalling $21,000 in 2002–03 for that client alone.

4.92 We recognize that short-term supervision may be necessary in some cases. Drugs such as methadone or those for dementia, other cognitive difficulties, or for clients in a nursing home may be exceptions; however, the requirement for full dispensing fees for each client for each prescription results in increased costs. We estimated that the programs of Veterans Affairs Canada and Health Canada paid dispensing fees for about one million transactions beyond services provided once a month for the same long-term drug; a third of these fees were for services provided more than once a week (average of close to five prescriptions per month for the same drug to the same client). With dispensing fees ranging from $6.54 to $9.53, we believe that federal organizations need to closely monitor pharmacists' practices for charging dispensing fees.

4.93 **Processing non-prescription products is expensive.** Some federal drug benefit programs pay for non-prescription products, such as acetaminophen, ASA, certain shampoos, and cold medicines. Typically, to receive federal payment for these products, the client has to visit a doctor, obtain a prescription, and then have a pharmacist provide the product and record the delivery of the benefit. In our 1996 audit of Veterans Affairs Canada's Health Care Program, we recommended that the Department explore less costly means of providing over-the-counter (OTC) medication to

its clients. The Department has done this but has not implemented a process to achieve significant cost savings.

4.94 In 2002–03, the drug benefit programs of Health Canada, Veterans Affairs Canada, the RCMP, and National Defence paid over $48 million in claims for over-the-counter drugs (Exhibit 4.11). About 40 percent of this cost was for dispensing fees or mark-ups. Provinces pay for consultations with doctors and any associated medical assessments while the federal government covers the cost of the product and the pharmacy dispensing fee. As currently structured, the process can be very costly to both the provincial and federal health care systems. For example, providing a client with a common OTC medication, such as a $7 bottle of vitamin C, could cost the federal and provincial governments more than $20.

Exhibit 4.11 Over-the-counter drug expenditures, 2002–03 ($ thousands)

Organization	Expenditures
Health Canada	40,885
Veterans Affairs Canada	5,577
National Defence	1,381
RCMP	245
Total	**$48,088**

4.95 Some organizations have made efforts to reduce costs. For those Canadian Forces members unable to access a base pharmacy for over-the-counter drug products, National Defence provides them with a special card that lists the OTC drugs the program will cover. A prescription is not required. Instead, qualified pharmacists document the OTC drug transaction and are reimbursed for the cost of the drug plus any necessary consultation costs. For National Defence, this consultation cost is similar to a dispensing fee but the doctor's fee is avoided. In some provinces and territories, Health Canada has established dispensing fees for over-the-counter drugs that are lower than the fees charged for dispensing prescription drugs. Citizenship and Immigration Canada and Correctional Service Canada do not provide appreciable over-the-counter benefits to their clients.

4.96 **Better strategies are needed for pharmacy audits.** The timely, strategic, and effective audit of pharmacies is an important tool, both to recover funds and to deter potential abuse. We expected that organizations would have a systematic and comprehensive audit strategy based on an assessment of risk aimed at identifying irregularities, errors, and fraudulent claims that are the most frequent and have the largest dollar-value billing.

4.97 Four of the organizations we examined (Health Canada, Veterans Affairs Canada, National Defence, and the RCMP) audit pharmacies through their service providers. Citizenship and Immigration Canada and Correctional Service Canada do not conduct pharmacy audits.

4.98 Health Canada has a robust audit program. It identifies pharmacies for audit through pharmacy profiling. This is a procedure that systematically reviews the claims history of each pharmacy through a series of weighted tests, based on risk and designed to assess inappropriate billing patterns. Every pharmacy is assessed in each reporting period and assigned a rank based on a composite test score reflecting a sophisticated risk-profiling process. The Profiling Review Committee at Health Canada makes the final selection of pharmacies for audit based on the composite test scores and all of the various assessments and reviews. The Department's contractor carries out the audits on its behalf.

4.99 In our 2000 follow-up chapter, First Nations Health, we recommended that Health Canada enforce the contract requirements for the audit of pharmacies. In our most recent audit, we found that the Department had substantially increased the number of audits of pharmacies. While it completed only 84 pharmacy audits during the three years ending March 2001, it completed 265 pharmacy audits during the subsequent three years ending March 2004.

4.100 We also found that the risk-profiling process appears to target appropriate pharmacies for audit. Of pharmacies that dispensed more than 15 prescriptions per client for the same drug in 2002–03, the top 10 pharmacies billed over $1.1 million for services to these clients. Each of these pharmacies has been subject to at least one on-site audit since April 2002.

4.101 Veterans Affairs Canada, National Defence, and the RCMP rely on the contractor to recommend pharmacies for audit based on their own profiling exercise and an analysis of trends of the previous reporting period. Management of Veterans Affairs Canada reviews recommendations of pharmacies to audit and can adjust the proposed audit plan. Health Canada's rigorous techniques for selecting pharmacies to audit are not replicated in any of these other organizations' programs. Furthermore, since all federal organizations use the same retail pharmacies across Canada for at least some of their clients, opportunities for joint audits and sharing of audit results are being missed.

4.102 **Amounts owing the Crown are not always collected.** Pharmacy audits do not always lead to recovery of overpayments identified. From April 1998 to March 2004, the claims administrator for Health Canada completed 349 pharmacy audits. These audits led to recovery of $1.7 million, but an additional $2.1 million has yet to be recovered. From 1999 to 2003, the claims administrator for Veterans Affairs Canada conducted 439 pharmacy audits. These audits led to recovery of $1.1 million, but an additional $700,000 is pending recovery.

4.103 National Defence administers most of its drug claims through base pharmacies and relies on Veterans Affairs Canada's claims administrator to identify and conduct audits of off-base pharmacies. The RCMP relies on the claims administrator to identify and conduct audits as it sees fit.

4.104 Once audits have been completed and amounts to be recovered have been determined, pharmacies may not have sufficient incentive to repay the amounts owing. The consequence of improper billing by a pharmacy is that the pharmacy must pay back the amount agreed as overcharged, with repayment terms arranged. While a pharmacy can be suspended from being a provider, Health Canada and Veterans Affairs Canada expressed concern that doing so may compromise the delivery of services to clients, particularly those in rural areas. These departments have not recorded the outstanding amounts owed by pharmacies in the Public Accounts as required by the Treasury Board Policy on Receivables Management.

4.105 Overall, federal organizations are currently not very effective in controlling costs. Despite the existence of advisory and co-ordinating mechanisms such as the Federal Pharmaceutical and Therapeutics Committee and the Federal Health Care Partnership, decisions on the provision of drug benefits are made with little attempt to reconcile differences between organizations. While we noted some efforts to contain costs, federal organizations were not systematically pursuing well-established strategies being used elsewhere.

4.106 **Recommendation.** The federal government should establish an arrangement, characterized by a centrally-managed process, which will permit it to

- develop and manage a core formulary common to all federal drug benefit programs,
- develop a common evidence-based process to ensure that all departmental exceptions to the core formulary will be made with appropriate transparency and accountability,
- obtain the best value for each drug product listed on the core formulary,
- establish a single federal schedule for dispensing fees,
- explore less costly means of processing over-the-counter benefits, and
- develop a common risk-profiling and auditing process for all pharmacy audits.

Government's response. Federal organizations agree to work together to explore cost-effective drug use and system efficiency as per this recommendation. In the longer term, as part of federal involvement in the development and implementation of the National Pharmaceutical Strategy, the federal government will ensure that the specific needs of federal client populations are reflected.

4.107 **Recommendation.** Health Canada and Veterans Affairs Canada should identify the amounts owing to the Crown resulting from pharmacy audits in the Public Accounts. In accordance with Treasury Board policy, Health Canada and Veterans Affairs Canada should institute procedures to expeditiously recover these amounts owing (including interest).

Departments' response. Agreed. Health Canada and Veterans Affairs Canada will identify amounts owing as a result of pharmacy audits, in the Public Accounts effective 2005-06.

Effective practices of federal organizations

4.108 The federal organizations we audited are managing parts of their programs very well. Because of the similarities in the programs, many of the better practices in one program could be applied to the others. A few of the most notable practices include the following:

- The Federal Pharmaceutical and Therapeutics Committee and the Federal Health Care Partnership seek to enhance the management of the provision of drug benefits for all federal organizations.
- Health Canada and National Defence adhere closely to the Federal Pharmaceutical and Therapeutics Committee.
- The National Defence Formulary Review Committee, comprised of medical specialists and postgraduate clinical pharmacists, has enhanced the Department's formulary to meet operational needs. These same experts are routinely used to address requests for limited-use benefit drugs, thereby ensuring sound, evidence-based decisions.
- National Defence, Correctional Service Canada, and Citizenship and Immigration Canada purchase drugs using competitive, low-cost acquisition practices. Citizenship and Immigration Canada eliminates brand name products from its formulary as generic equivalents become available.
- Veterans Affairs Canada, Health Canada, the RCMP, and National Defence use claims processing systems with the capability of performing multiple checks and efficient processing of tens of thousands of transactions at a time. While our audit points to the need to enhance the point-of-service support provided to pharmacies, the basic capacity is already in place.
- Veterans Affairs Canada, National Defence, and the RCMP have teamed up to use a common claims processing administrator.
- Health Canada has established a reduced dispensing fee for over-the-counter drug products for some provinces and territories, which could lead to significant savings if applied nationally to all programs that supply these products.
- Health Canada uses comprehensive risk-profiling techniques to identify pharmacies for audits.
- Veterans Affairs Canada conducts patient-based drug utilization review, targeting high-risk clients; though not comprehensive, the system is oriented to health and safety.

4.109 If all federal drug benefit programs used some of the practices listed above, and other favourable practices identified elsewhere in this chapter, we believe that the benefit from such opportunities would be significant, without negatively affecting health outcomes or compromising operational activities.

Timely and effective analysis of drug use trends could also lead to positive health outcomes for clients.

Conclusion

4.110 In this audit we examined how the federal government ensures that its clients receive appropriate drug benefits and how the federal government manages its costs.

4.111 Although all federal drug benefit programs have a mandate, most organizations have not established clear objectives and performance measures for their drug benefit activities. As a result, they lack the necessary information for reporting to Parliament on the performance of their drug benefit programs.

4.112 Organizations do not use the substantial information on drug use in their databases to analyze and encourage appropriate practices. Our audit found several important patterns of drug use that organizations had not identified. It also found that Health Canada had not conducted drug use analysis it had committed to do in previous audits and to the Public Accounts Committee.

4.113 Federal organizations are not taking sufficient measures to contain costs. Organizations' management of their drug formularies is inconsistent and they are not doing enough to minimize the costs of drugs they provide. We believe that numerous opportunities for significant savings could be more fully realized if actively pursued.

4.114 Organizations have made notable progress on some recommendations from our past audits. We believe that increased sharing of best practices among the organizations would help to correct deficiencies that still exist in their drug benefit programs and result in substantial cost savings.

4.115 We also believe that prompt attention to the many issues raised in this audit is in the interest of taxpayers and, most important, in the interest of the approximate one million clients who depend on these programs.

Overall government response. The organizations agree with all of the recommendations. The recommendations support and build on the commitments of the First Ministers to develop and implement a National Pharmaceutical Strategy to address concerns faced by all jurisdictions. The Strategy provides the foundation for new approaches to promote cost-effective drug use and system efficiency, to the advantage of clients and taxpayers. The organizations are committed to ongoing collaboration in the development and implementation of the Strategy. Decisions on the specifics and timing of the responses are underway and will be communicated to the Office of the Auditor General within a few months.

About the Audit

Objectives

The Canadian Council of Legislative Auditors (CCOLA) developed the first six objectives and corresponding criteria for this audit as a means of standardizing the approach taken by the federal government and provinces in planned concurrent audits of respective drug benefit programs. In addition to addressing these objectives, we followed up on previous audits in this area and assessed best practices.

The objectives of our audit included the following:

- to assess whether the organization has adequate procedures in place to measure the performance of the drug/pharmacare program;
- to assess whether the organization monitors the quality and relevance of drug use and encourages appropriate and economical practices;
- to assess whether the organization has adequate procedures in place to ensure that resources are managed with due regard for cost-effectiveness;
- to assess whether the organization has adequate procedures in place to ensure the eligibility of the insured persons and appropriate collection of premiums and other fees;
- to assess whether the organization has adequate procedures in place to ensure compliance with legislation and whether its policies and procedures for approving, processing, and paying claims are adequate and are being followed;
- to assess whether there is adequate reporting on the drug/pharmacare program's performance and whether reports to Parliament/legislature are presented in the prescribed timeframe;
- to assess whether organizations have taken satisfactory action on deficiencies identified in previous audits; and
- to assess the extent to which federal drug benefit programs have incorporated best practices from other federal programs, from provincial government programs, and from private sector and international programs.

Scope and approach

The focus of this audit was all federally sponsored drug benefit programs. We examined programs in Citizenship and Immigration Canada, Correctional Service Canada, Health Canada, National Defence, the Royal Canadian Mounted Police, and Veterans Affairs Canada.

We examined the mandates of the organizations and the various programs' eligibility rules. We also examined the management controls for claim payments in each program. This included a review of the contracts between the organizations and the claims processors. We analyzed the organizations' formularies as well as the mandate and proceedings of the Federal Pharmaceutical and Therapeutics Committee. We also analyzed the organizations' drug use and transaction databases. Where relevant, we relied on audits conducted by other organizations. We did not audit individual drug benefit transactions.

We examined the action taken by Health Canada in response to our 2000 recommendations as well as the action taken by Veterans Affairs Canada in response to our 1996 recommendations on non-insured health benefits. We interviewed departmental staff involved in the non-insured health benefits programs. We reviewed documentation, including legislation, regulations, program documents, and studies, and we reviewed all information collected for best practices. To conduct our data analysis, we obtained anonymized data of all organizations' programs, where available, from 2002–03 and available data for 2003–04.

To complete our analyses of seniors receiving 10 or more drugs simultaneously (paragraph 4.56), we selected simple samples from four separate populations. The sample sizes were sufficiently large to render confidence intervals of plus or minus 10 percent, at a 95 percent or higher level of confidence for each population. Predictions of the combined

populations were calculated using weighted averages. The confidence intervals of these predictions were no larger than plus or minus 5 percent, at a 95 percent level of confidence.

To complete our analysis of federal and provincial price comparisons (paragraph 4.71), we rounded volume purchases and excluded all outliers. We conducted statistical tests of price variation of drugs over a calendar year and of potential variation in prices caused by possible differences in the costs of drugs between provinces. We found the price differences to be minimal.

Criteria

Like the audit objectives, criteria for this audit were developed by the Canadian Council of Legislative Auditors (CCOLA). Common objectives and criteria were used as a means of standardizing the concurrent audits of respective drug programs of the federal, provincial, and territorial governments. The pertinent criteria reported against in this audit are as follows:

- The objectives of the program should encompass the entire program mission. They should be well defined, measurable, and periodically reviewed.
- Adequate performance information should be available to measure whether the program's mission statement and objectives are being achieved.
- An adequate responsibility framework should be put in place with the third-party service provider in order to evaluate the effectiveness of its services (expectations, appraisal, and ways to account).
- Adequate procedures should be in place to ensure compliance with legislation and policies and to take corrective action when necessary.
- Drugs to be listed should be properly assessed to ensure that they are cost-effective.
- Drugs listed should be regularly evaluated to determine whether they should be retained, deleted, or restricted in their use, and corrective action should be taken when necessary.
- Policies and processes should be in place to ensure that listed drugs and pharmacy services are acquired at the lowest possible cost (including use of competitive processes, generic drugs, and volume discounts).
- Prices of drugs should be followed up and analyzed and, if necessary, audited.
- Prescribing practices should be monitored to assess and, to the extent practical, determine whether they are appropriate and economical.
- Procedures should be in place to encourage improved prescribing practices for doctors.
- Procedures should be in place to monitor and analyze drug use and to take corrective action when necessary (for example, over-prescribing and potential drug interaction).
- Adequate procedures should be in place to identify and prioritize pharmacies for audits.
- Audits should be consistently conducted and, where applicable, recoveries should be made on a timely basis.
- The organization should have reasonable assurance that the pharmacy payment system processes only valid claims accurately, consistently, and on a timely basis, and that the amounts paid to pharmacies comply with the policies and legislation.
- The reported information should be presented to Parliament/legislature in the prescribed timeframe.
- Health Canada should have taken appropriate action on the Office of the Auditor General's 2000 follow-up audit of the Department's drug benefit program.
- Veterans Affairs Canada should have taken appropriate action on the Office of the Auditor General's 1998 follow-up audit of the Department's drug benefit program.

Other related audit work

See the following reports of the Auditor General: Chapter 13, Health Canada—First Nations Health (October 1997); Chapter 15, Health Canada—First Nations Health Follow-Up (October 2000); Chapter 12, Veterans Affairs Canada—Health Care (May 1996); and Chapter 28, Veterans Affairs Canada—Health Care Follow-up (December 1998).

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Appendix Follow-up of previous audits

2000 Office of the Auditor General recommendation	2001 Public Accounts Committee recommendation	Our assessment	Progress to date
Health Canada should more closely monitor pharmacists' overrides of drug utilization messages and undertake rigorous analysis on an ongoing basis to assess the effectiveness of the messages.	That Health Canada regularly analyze overrides of warning messages generated by the point-of-service system to determine whether warning messages are effective, whether prescriptions rejected by some pharmacists have been filled by others, and how and why clients with very large numbers of prescriptions are getting through the system.	●	Health Canada continues to monitor overrides of warning messages and uses that information to determine which provider should be audited. (see paragraph 4.29)
	That Health Canada include a discussion of its analysis of pharmacists' overrides along with subsequent action taken in response to that analysis in its performance reports beginning with the report for the period ending 31 March 2002.	●	Health Canada has reported in its performance report on the analysis of pharmacists' overrides and action taken. (see paragraph 4.29)
	That Health Canada immediately upgrade the point-of-service system for pharmacies under the Non-Insured Health Benefits Program so that the system provides the dates, quantities, and drugs prescribed of at least a client's last three prescriptions and information on doctor visited.	○	The data extracted from the point-of-service system in Health Canada have not been updated as requested by the Public Accounts Committee. (see paragraph 4.34)
In cases where it identifies a significant pattern of inappropriate use of prescription drugs, Health Canada should continue to perform rigorous follow-up with Non-Insured Health Benefits clients, physicians, pharmacists, and professional bodies. Health Canada should ensure that it has the means to implement this action.	That Health Canada implement a centralized analysis of drug use similar to that found in the provinces in order to identify misuse, abuse, and multiple use on a real-time basis.	○	Clients at Health Canada continue to access large numbers of prescription drugs. Information drawn from the overrides is not used to conduct drug utilization review and monitor patient safety. (see paragraph 4.33)
	That Health Canada develop a policy to guide its response in cases where it is unable to obtain the consent of recipients of Non-Insured Health Benefits to share information on use of pharmaceuticals with health care professionals and make that policy known prior to the implementation of a client consent arrangement under the Non-Insured Health Benefits Program.	◒	Health Canada has discontinued analysis of inappropriate drug use due to privacy concerns, despite the fact that sharing of client profiles is not necessary. (see paragraph 4.46)
	That Health Canada explore ways of facilitating the sharing of information between individual pharmacists and physicians providing services under the Non-Insured Health Benefits Program and report its conclusions to the Committee by 31 March 2002.		

● Fully addressed ◒ Satisfactory progress ○ Unsatisfactory progress

2000 Office of the Auditor General recommendation	2001 Public Accounts Committee recommendation	Our assessment	Progress to date
	That Health Canada ask the government to amend the *Privacy Act* if necessary in order to clarify that health care providers can share the personal medical information of individuals among other health care providers.		
	That Health Canada review the option of obtaining specific enabling legislation for the Non-Insured Health Benefits Program that would, among other things, permit sharing of information about client drug prescription patterns among health care professionals, and report the conclusions of that review to the Committee by 31 March 2002.		
Health Canada should enforce the contract requirements for audit of pharmacy and dental care providers and reporting by the contractor. The Department should continue to take steps to strengthen verification of claims and audit of providers.	That Health Canada include the evaluation plans for community health programs and the Non-Insured Health Benefits Program in its Report on Plans and Priorities, beginning with the report for the fiscal year 2002–03.	◓	Health Canada has taken steps to address overpayment. Next-day claim verification and pharmacy audits have resulted in the prevention, detection, and recovery of overpayment. (see paragraphs 4.99 and 4.102)
1996 Office of the Auditor General recommendation	**2001 Public Accounts Committee recommendation**	**Our assessment**	**Progress to date**
Veterans Affairs Canada should develop and implement a plan to realize the benefits of the revised drug formulary and improved drug-monitoring system.		●	Veterans Affairs Canada completely overhauled its formulary and implemented a claims processing system in 1997–98. (see paragraphs 4.31)
Veterans Affairs Canada should explore less costly means of providing over-the-counter medication to clients.		◓	The Department has explored less costly means of providing over-the-counter drugs but has not implemented a process that would lead to significant cost savings. (see paragraphs 4.93)

● Fully addressed ◓ Satisfactory progress ○ Unsatisfactory progress

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