

3.09—Drug Programs Activity

BACKGROUND

Ontario’s drug programs are administered by the Drug Programs Branch (Branch) of the Ministry of Health and Long-Term Care. The Branch co-ordinates ministry policies and activities associated with the provision of prescription drugs and related products to eligible residents of Ontario. The Branch’s mission is “to provide leadership in achieving optimal pharmaceutical services for the protection and improvement of the health status of residents of Ontario.” In that regard, the Branch’s objectives include:

- achieving equitable protection for Ontarians from unaffordable drug costs; and
- containing costs with suitable controls to keep Ontario’s prescription drug programs affordable.

The Branch is responsible for administering transfer payments provided by the Ministry’s Drug Programs Activity for the following drug programs:

Ontario Drug Benefit Program: provides prescription drugs to Ontario seniors, social-assistance recipients, individuals receiving professional home-care services, and residents of homes for special care or long-term care facilities. Since 1996, recipients must contribute towards the cost of prescription drugs paid for by the Program. The Ontario Drug Benefit Program accounts for approximately 38% of all prescription drug expenditures in Ontario.

Trillium Drug Program: provides assistance to people who do not meet the eligibility requirements of the Ontario Drug Benefit Program and who have high prescription drug costs in relation to their income.

Special Drugs Program: provides funding to cover the costs of certain drugs required for the treatment of specific health conditions as set out in regulations under the *Health Insurance Act*.

Legislative authority for transfer payments made through Ontario’s drug programs is established under the *Ontario Drug Benefit Act*, the *Drug Interchangeability and Dispensing Fee Act*, and the *Health Insurance Act*.

The Branch is also responsible for monitoring the development, operation, and maintenance of the Health Network System (Network)—a computer system that links the Branch to approximately 2,700 pharmacies and 600 other dispensers; provides on-line information to pharmacists; and enables the submission, adjudication, and payment of drug claims. The

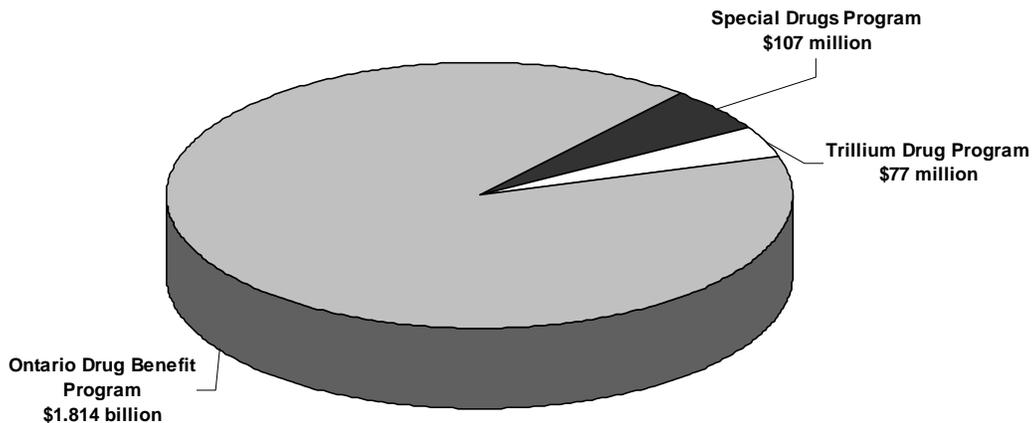
Network, which annually processes approximately 50 million prescriptions for approximately 2.7 million eligible recipients, is operated on behalf of the province by a private-sector service provider.

The Drug Quality and Therapeutics Committee, which was established in 1968 under the *Ministry of Health Act*, evaluates the quality, therapeutic value, interchangeability, and cost of drugs, as well as their suitability for funding by the Ministry.

The Branch manages the delivery of the drug programs with the assistance of expert advisory committees. In 1998, the Drug Utilization Advisory Committee was established to review issues related to the utilization of prescription drugs, and the Ontario Program for Optimal Therapeutics Committee was established to oversee the development of additional prescribing guidelines and related projects.

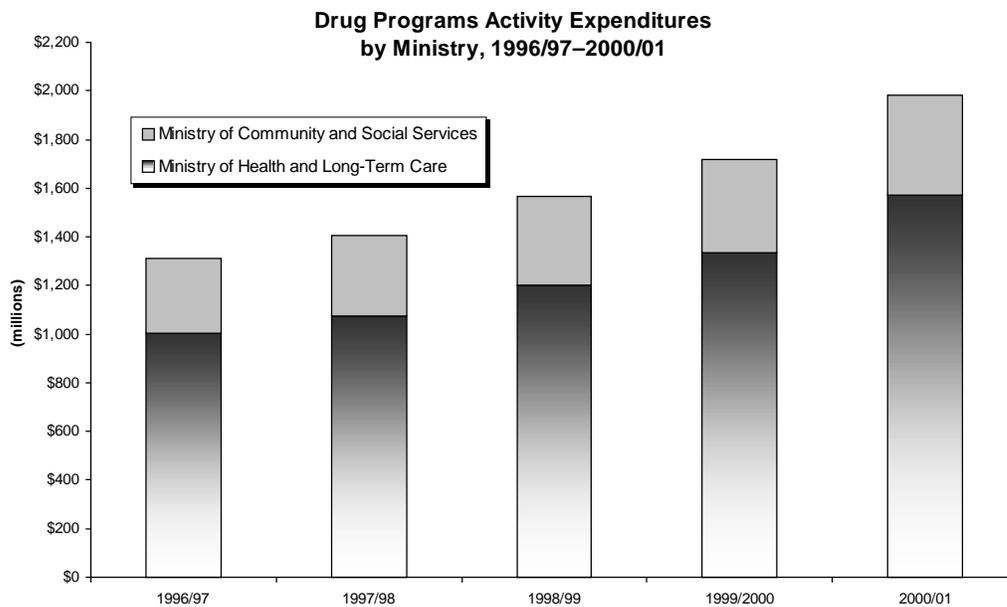
For the 2000/01 fiscal year, Ontario's drug programs had total expenditures of \$1.98 billion—\$413 million of which was recovered from the Ministry of Community and Social Services for drug benefits paid for social-assistance recipients. In addition to ministry expenditures, drug expenditures included recipients paying \$250 million in deductibles and co-payments. The following graph illustrates the expenditures of the three drug programs.

**Ontario Drug Programs Activity
Expenditures by Program, 2000/01**



Source of data: Ministry of Health and Long-Term Care

Transfer payments for the Drug Programs Activity have increased by approximately 51% from 1996/97 to 2000/01, as illustrated by the following graph.



Source of data: Ministry of Health and Long-Term Care

Jurisdictions other than Ontario are also reporting significant annual increases in prescription drug expenditures for their publicly funded drug plans. Various health-related reports indicate that a number of factors are contributing to these increases, including:

- an increase in the number of residents 65 years and older;
- the introduction of new and more expensive drugs and drug therapies that allow patients to remain in their homes longer or leave hospitals sooner; and
- changes in prescribing practices.

In April 1998, the government approved six cost-management initiatives recommended by the Cabinet Committee on Financial Planning to contain annual drug program expenditures. These initiatives included: modernizing the Ontario Drug Benefit Program Formulary, introducing written agreements with manufacturers, establishing a new generic pricing rule, and developing new prescribing guidelines. Despite these initiatives, Ontario Drug Programs Activity expenditures have continued to increase by 7% to 15% annually.

AUDIT OBJECTIVES AND SCOPE

The objectives of our audit of the Drug Programs Activity were to assess whether the Ministry had adequate procedures in place to:

- ensure resources were managed with due regard for economy;
- ensure compliance with legislation and assess whether its policies and procedures for approving, processing, and paying claims were adequate and were being followed; and
- measure and report on the effectiveness of the Drug Programs Activity.

Our audit was conducted in accordance with the standards for assurance engagements, encompassing value for money and compliance, established by the Canadian Institute of Chartered Accountants and accordingly included such tests and other procedures as we considered necessary in the circumstances. Prior to the commencement of our audit, we identified the audit criteria that would be used to address our audit objectives. These criteria were reviewed and agreed to by senior ministry management.

In conducting our audit, which was substantially completed in May 2001, we reviewed and analyzed relevant policies and procedures and interviewed ministry staff in Toronto and Kingston, as well as staff of the Health Network System service provider. We also reviewed the operations of the Health Network System and the relevant work completed by the Ministry's Audit Branch. In addition, we met with members of the Drug Quality and Therapeutics Committee and the Ontario Program for Optimal Therapeutics Committee, researchers at the Institute for Clinical Evaluative Sciences in Ontario, and medical experts at the Centre for Evaluation of Medicines.

OVERALL AUDIT CONCLUSIONS

Since our last audit of the Drugs Program Activity, the Ministry has introduced a number of initiatives to manage drug expenditures, including initiatives to encourage appropriate prescribing and improve the timeliness of updates to the Formulary.

However, with respect to due regard for economy, the Ministry had not given sufficient consideration to the prices it was paying for drugs and had not completed the development of a drug use review program. We raised similar concerns in our 1996 audit of this area.

Our major concerns with respect to prices paid for drugs are as follows:

- The Ministry had not maximized savings from the addition of approved generic drugs to the Formulary or from manufacturers' price reductions. Based on a sample of drugs we reviewed, we estimated that delays over a two-year period resulted in lost savings totalling \$17 million.
- The Ministry had not reviewed the effectiveness of its generic pricing practices or routinely compared the prices it was paying for drugs with the prices paid by other jurisdictions. For instance, for a sample of generic drugs, we noted that Saskatchewan's prescription drug plan prices were on average 50% lower than Ontario's. We estimated that the Ministry would have saved approximately \$54 million annually had it paid the same price as Saskatchewan for these products.
- The Ministry had not assessed the benefits of acquiring drugs from manufacturers through a competitive process. For instance, we reviewed a sample of drug prices paid by another jurisdiction using a competitive acquisition process and found that if Ontario's drug programs were able to obtain these drugs at the same prices, they would have been able to save approximately \$140 million in the 2000/01 fiscal year. While Ontario may not be able to obtain the same prices as the other jurisdiction, the significant difference in price warrants further examination.

In general, we found that while the Ministry had adequate procedures in place to ensure compliance with legislation and that claims were properly approved, processed, and paid, the Ministry still needed to:

- ensure that individuals granted temporary eligibility for the drug programs are subsequently confirmed as being eligible—although approximately 335,000 individuals were granted temporary eligibility during the 1999/2000 fiscal year, the Ministry had not substantiated the eligibility of as many as 180,000 of them;
- better identify and follow up on incorrect or false billings by inspecting pharmacies and verifying claims with recipients;
- recover inappropriate payments on a timely basis—in 2001, the Ministry forgave \$1.5 million to be recovered from pharmacies as a result of a 1997 verification of claims for limited-use drugs;
- implement procedures to ensure that deductibles under the Trillium Drug Program are properly applied—for the 1999/2000 benefit year, approximately \$750,000 was owing to the Ministry for outstanding deductibles;
- improve the procedures for paying Special Drugs Program invoices—we found that, for one drug we selected for audit, the Ministry had been overcharged \$475,000 over a five-year period (the Ministry was in the process of recovering the overpayment from the manufacturer); and
- better monitor the activities of the Health Network System service provider and ensure adequate computer security processes were in place.

We also concluded that to provide better accountability to the public and the Legislature, the Ministry needed to develop a comprehensive set of performance measures and periodically report publicly on the performance of the Drug Programs Activity.

DETAILED AUDIT OBSERVATIONS

ONTARIO DRUG BENEFIT AND TRILLIUM DRUG PROGRAMS

Drug Use Review

When used appropriately, prescription drugs can be a cost-effective form of treatment, often preventing or reducing an individual's need for hospitalization or long-term residential care. However, increasing drug expenditures do not necessarily indicate that Ontario's drug programs are achieving their goal of protecting and improving the health status of the residents of Ontario.

The health-care experts we met with indicated that inappropriate prescribing and patients' failing to follow their prescribers' instructions are significant problems. Inappropriate prescribing includes unnecessary prescribing, prescribing an expensive drug rather than a cheaper and equally effective alternative, and prescribing the wrong drug or the wrong dose. In addition, these experts indicated that research had shown that not prescribing drugs in cases where they

should have been prescribed may affect patient care and may increase pressure on other parts of the health system. When inappropriate use is identified, the measures used to address the problem depend on the reasons for inappropriate drug use: measures could include providing prescribers with information on their prescribing relative to their peers, as well as educational visits to discuss prescribing practices for specific medical conditions.

In our *1996 Annual Report*, we noted that the Ministry had taken a number of steps to encourage appropriate prescribing. These included sponsoring the development of prescribing guidelines to assist prescribers in determining the most clinically correct and cost-effective drugs for certain infections and uncomplicated hypertension.

In 1998, the Ministry established the Ontario Program for Optimal Therapeutics Committee to oversee the development of additional prescribing guidelines and related projects. In 1999, the Ministry had provided \$4.3 million in funding to the Committee. By the end of our current audit, the Committee had commissioned the development and issuance of seven prescribing guidelines covering the treatment of certain conditions such as diabetes and arthritis. However, we were advised that the Committee had not yet decided on implementation strategies for the guidelines.

While prescribing guidelines are an important step in encouraging appropriate prescribing, research has consistently shown that, by themselves, guidelines do not change prescribing practices. Given this, in 1996, we recommended that the Ministry ensure the establishment of a drug use review program to promote the appropriate and economical prescribing of drugs. Drug use review is an ongoing process that analyzes prescribing patterns, as well as the use of drugs by patients, against established criteria. It would also include the design and implementation of measures to improve drug use.

In response to our recommendation, the Ministry stated that it supported drug use review and was working with the Ontario Pharmacists' Association towards an agreement to institute drug use review.

In providing pharmacists with on-line warnings about drug interactions through its Health Network System, the Ministry already has in place some elements of drug use review. In addition, according to ministry officials, prescribers in primary care networks will eventually be able to access the Network's database to check for possible interactions before writing a prescription. Health experts have indicated that one of the most promising ways of assisting prescribers is to provide them with information through computer software about alternative treatments and costs when they are making decisions about appropriate treatment.

Nevertheless, despite recommendations that date back to 1990 with the Pharmaceutical Inquiry of Ontario, the Ministry has not established a drug use review program. We noted that some other jurisdictions—including at least two other Canadian provinces (Saskatchewan and Quebec) and the United States Medicaid Program—have such programs in place.

The success of any drug use review program depends in part on the completeness and accuracy of the information used to assess the appropriateness of drug use. Despite the need for complete and accurate information, we found that, in the past two years, 10% of claims did not identify the prescriber. It may also be beneficial to link prescription information in the Health Network System with information about a patient's medical diagnosis in the OHIP database to assess whether the prescriptions appear appropriate.

Recommendation

To help ensure that Ontario's drug programs encourage the economic and appropriate use of prescription drugs and result in optimal improvement in the health status of recipients, the Ministry, in consultation with other stakeholders, should:

- establish a drug use review program; and
- ensure that the Health Network System provides accurate and complete information to implement drug use review.

Ministry Response

The Ministry is promoting appropriate prescribing and utilization reviews with other stakeholders in several ways:

- *The Ontario Program for Optimal Therapeutics (OPOT) developed and disseminated seven sets of guidelines in January 2001, which cover over 50% of drugs funded. These guidelines, which reflect up-to-date, expert consensus on specific therapeutic categories, were distributed to physicians and pharmacists and are being used widely within Ontario and by other provincial jurisdictions. OPOT will assess the utilization and promotion of prescribing guidelines.*
- *The mandate of the Drug Utilization Advisory Committee includes encouraging the appropriate use of prescription drugs, reviewing utilization of prescription medications, and identifying factors that affect usage and actions that are required to ensure utilization is rational and changes are predictable. This committee is supported by the brand-name pharmaceutical industry and the Ministry.*
- *The Ministry has supported various initiatives related to the evaluation of drug utilization through work done with the Institute for Clinical Evaluative Sciences.*

The Ministry has consulted with the College of Physicians and Surgeons of Ontario about providing an updated list of physician identification numbers to pharmacies. To ensure information on the Health Network System is accurate and complete, pharmacies are being instructed that valid identification numbers must be used unless the situation is exceptional.

The Drug Formulary

The Ontario Drug Benefit Formulary/Comparative Drug Index (the Formulary) lists the approximately 3,100 drug products that are covered by the Ontario Drug Benefit and Trillium Drug programs along with the prices that the Drug Programs Branch will generally pay pharmacists for these drugs. The Formulary also identifies “those brands of drugs that are considered to be interchangeable, and serves as a prescribing and reimbursement guide for doctors and pharmacists.”

Before a drug product is listed in the Formulary, drug manufacturers must make a submission to the Branch. This submission is reviewed by the Drug Quality and Therapeutics Committee, which considers how well the drug works and whether it is cost effective when compared to other drugs having similar results. Based on its review, the Committee may recommend to the Minister that the drug be listed on the Formulary.

The Branch prepares an analysis of the Committee's recommendations for review by the Ministry's senior management. Final recommendations—along with other revisions to be made to the Formulary, such as price changes—are forwarded to the Management Board of Cabinet for approval. Approved additions or revisions are included in the Formulary in accordance with regulations made under the *Ontario Drug Benefit Act*.

Since our 1996 audit, the Branch has introduced a number of measures to streamline the drug submission, review, and evaluation process. These measures have included removing administrative barriers and, where possible, harmonizing its processes with those of Health Canada. For instance, since September 2000, when Health Canada issues a Notice of Compliance indicating that a generic drug is bioequivalent to a specific brand-name drug, the generic drug bypasses Ontario's normal committee review process and is added directly to a formulary update.

TIMELY UPDATES TO THE FORMULARY

Delays in having drugs listed in the Formulary, particularly generic drugs, can be costly to the Ministry. For instance, promptly listing generic drugs, which are lower-priced bioequivalents of brand-name drugs, saves the Ministry money. During our 1996 audit, the Ministry advised us that part of the Drug Program Branch's continuous review cycle was to fast-track the addition of products to the Formulary. In November 1998, the Ministry committed to quarterly updates of the Formulary.

During this audit, we reviewed the recommendations made by the Drug Quality and Therapeutics Committee between June 1999 and November 2000 and noted that of 182 generic and brand-name drugs that were recommended for listing, 142 were not included in the next formulary update. For 83 of these drugs, the Committee's recommendations were made a full one to three months prior to the next update. However, the need for subsequent review and approval delayed the listing of these products.

The Branch calculated that, as a result of generic drugs added to the Formulary between December 1998 and November 2000, the Ministry was saving \$57 million annually. From these drugs, we selected a sample that represented approximately 50% of the savings identified and found that, on average, eight months had elapsed between these drugs being recommended and being listed on the Formulary, which resulted in lost savings to the Ministry totalling approximately \$16.7 million.

In our *1996 Annual Report*, we recommended that to avoid paying more than is necessary for drugs, the Ministry should ensure that drug manufacturers' price reductions are incorporated in the Formulary on a timely basis. At that time, it took an average of six-and-a-half months to implement the reductions. During this audit, we found that price reductions were still not being incorporated on a timely basis. Between December 1998 and November 2000, drug manufacturers voluntarily requested price reductions for a number of drugs. The Branch estimated that, once implemented, these reductions would save the Program approximately \$2.4 million annually. We reviewed drugs that represented approximately 65% of the estimated

savings and found that, on average, it took eight months for the price to be reduced on the Formulary, resulting in lost savings to the Ministry totalling approximately \$840,000.

The Ministry advised us that, despite the potential significant savings, there were no processes for expediting the listing of drugs recommended by the Committee or the implementation of manufacturers' price reductions on the Formulary.

Recommendation

To help maximize potential savings to the Drug Programs Activity, the Ministry should pursue more timely updating of the Ontario Drug Benefit Formulary when:

- adding approved generic drugs; and
- implementing manufacturers' price reductions.

Ministry Response

The Ministry has been making quarterly updates to the Ontario Drug Benefit Formulary for the past three years. Nine updates have been issued since December 1998.

The Ministry has endeavoured to strike a balance between enhancing efficiency and ensuring that drug review procedures are cost effective and meet the needs of Ontario Drug Benefit recipients.

With respect to the \$16.7 million that was identified by the auditor as a lost savings arising from delays in listing generic products, in each case the product was listed in the Formulary Edition or Update as per standard process. Five of the 12 products identified were approved prior to the December 31, 1998 update. There were no Formulary updates from August 1997 to December 1998. The average time period before the listing of the other seven products, after December 1998, was four-and-a-half months, versus fourteen-and-a-half months prior to December 1998.

FORMULARY MODERNIZATION

In our *1996 Annual Report*, we recommended that the Ministry regularly re-evaluate all drugs listed in the Formulary to ensure that the Ontario Drug Benefit Program only covers drugs that are appropriate and cost effective. In 1998, to address one of the cost-management initiatives recommended by the Cabinet Committee on Financial Planning, the Ministry asked the Drug Quality and Therapeutics Committee to undertake a modernization of the Formulary. The Committee established a Modernization Subcommittee to review drugs by therapeutic category to ensure that the drugs listed continued to provide benefits, based upon current clinical knowledge and practice, and were cost effective.

During our current audit, we noted that the Ministry acted on most of the Subcommittee's recommendations approved by the Drug Quality and Therapeutics Committee in 1998. The Subcommittee had recommended 85 drugs be considered for delisting once consultations were

held with the various manufacturers; however, the Branch did not arrange for such consultations, and these drugs remained in the Formulary.

Between April 1998 and October 2000, various other subcommittees of the Drug Quality and Therapeutics Committee reviewed approximately 500 drugs from seven therapeutic categories, representing approximately 16% of the drugs on the Formulary. As a result, some drugs were delisted while others were identified as drugs that should only be covered for specific conditions.

Continuous formulary review is important to confirm whether drugs should be delisted, continue to be listed, or only be covered for specific conditions. While the Drug Quality and Therapeutics Committee and the Branch acknowledged the importance of formulary reviews, we were advised that there is no plan to conduct such reviews on a regular basis.

Recommendation

The Ministry should ensure that drugs listed in the Ontario Drug Benefit Formulary are regularly reviewed so that the Ontario Drug Benefit Program only covers the cost of drugs that are appropriate and cost effective.

Ministry Response

Over the past three years, eight comprehensive category reviews have been conducted by the Drug Quality and Therapeutics Committee (DQTC) and implemented in the Drug Formulary.

The DQTC and the Branch will continue to carry out reviews of medications that are reimbursed under the drug programs on a regular and ongoing basis to ensure that the Formulary remains up-to-date and in keeping with the latest clinical evidence.

Pricing

In our 1991 and 1996 *Annual Reports*, we recommended that the Branch regularly obtain information on the drug prices paid by other provinces to enable it to more effectively negotiate prices with drug manufacturers. In 1996, the Ministry responded that it was now doing this “on a consistent and regular basis through receipt of drug and drug policy analyses and Formularies from other provinces.”

In addition, in its 1996/97 Annual Report, the Standing Committee on Public Accounts issued the following recommendation: “Considering the number of [Ontario Drug Benefit] recipients and the resulting volume of sales, the Ministry should ensure that the prices paid for drugs listed in the Ontario Drug Benefit Formulary do not exceed the prices paid for the same drugs in other provincial jurisdictions.”

During our current audit, we compared the prices Ontario paid for drugs with those paid by the drug plans of Quebec and Saskatchewan for a sample of drugs that accounted for a significant portion of the Ontario Drug Benefit Program’s expenditures. While the prices were generally similar for most brand-name drugs, we found that for one major brand-name drug, both Quebec

and Saskatchewan paid lower prices. If Ontario had obtained the same price as Quebec, which had secured the lowest price, the Ministry would have saved approximately \$5 million annually.

As well, in 1998, the Cabinet Committee on Financial Planning recommended that a generic pricing rule be introduced to reduce the prices paid for generic drugs. The Ministry's policy is that the maximum price the Ontario Drug Benefit Program will pay for the brand-name drug and all generics in each category of drugs is usually the price of the lowest-priced generic in the Formulary. Accordingly, the addition of lower-priced generics results in immediate savings to the Program.

In May 1998, a new regulation under the *Ontario Drug Benefit Act* was approved requiring that, when the first generic of a brand-name drug was added to the Formulary, the price had to be 60% or less of the original price of the brand-name product. The prices of the second and subsequent generics had to be 54% or less of the original brand-name price. In November 1998, a revised regulation increased the maximum price at the introduction of the first generic to 70% and the second and subsequent generics to 63% or less of the brand-name price.

We obtained a report from the Branch on new generic drugs added to the Formulary between December 1998 and November 2000 and found 133 generic drugs were added without any savings to the Ministry. The primary reason for this was that prices approved for third and subsequent generics of a respective brand-name drug were all 63% of the original price of the brand-name drug. Savings to the Ministry would only accrue if generics were priced below 63% of the brand-name drug. Increased competition with the brand-name drug and between generic drugs trying to increase their market share creates greater opportunities for drug wholesalers and pharmacists to obtain lower prices from manufacturers. The Ministry, however, could still be paying pharmacists the higher formulary price.

We also noted that where the first and subsequent generics were added to the Formulary simultaneously, the price for all of these was 70% of the original price of the brand-name drug. We also found one instance where a second and third generic were added, but the price was not reduced from 70% to 63% of the price of the brand-name drug. Accordingly, the Ministry was not in compliance with its regulation and was therefore not benefiting from the addition of these generics.

We also assessed the impact of the generic pricing rule by selecting a sample of generic drugs and comparing the prices Ontario pays with the prices paid by Quebec and Saskatchewan. Quebec's prices were somewhat lower. Saskatchewan's prices, where it had tendered for these drugs, were on average 50% lower than Ontario's. Although Saskatchewan is a smaller purchaser of drugs than Ontario, it secured lower prices by tendering on a competitive basis for certain generic drugs. We estimated that Ontario could save approximately \$54 million annually if it paid the same prices as Saskatchewan for these generic drugs.

Recommendation

To better control the drug costs of Ontario's drug programs and to enable the Ministry to more effectively negotiate prices with drug manufacturers, the Ministry should routinely compare the prices it pays for drugs with the prices paid by other provinces.

The Ministry should also review the generic pricing rule to ensure that it does not impede the Ministry from obtaining generic drugs at the lowest possible price.

Ministry Response

Prices are set in agreements between the Ministry and the manufacturer in accordance with the regulations now in place.

As part of the work being done by the Federal/Provincial/Territorial Working Group on Drug Prices, a study was conducted comparing the retail prices for all drugs claimed under the programs of six provinces: Nova Scotia, Ontario, Manitoba, Saskatchewan, Alberta, and British Columbia. The results of the study indicate:

- *For patented drugs, Ontario was the lowest-cost province. On average, Ontario prices were 1.5% lower than Canadian prices.*
- *For non-patented drugs, Saskatchewan was the lowest-cost province and Ontario was the next lowest. On average, Ontario prices were 2.4% lower than Canadian prices.*
- *For generic products, Saskatchewan was the lowest-cost province and Ontario was the next lowest. Ontario prices were on average 1.3% below the Canadian average.*

The Ministry will review the generic price rule to ensure that Ontario receives the lowest possible price.

PRICING OPTIONS

Reference Drug Pricing

Since 1995, British Columbia has used reference drug pricing for certain categories of drugs to encourage the prescribing of less expensive drugs without sacrificing the quality of care provided to patients. British Columbia's drug plan covers the cost of the "reference drug"—usually the least expensive drug used to treat a particular medical condition. Independent experts provide advice on the categories of drugs where reference pricing can be applied. While for most people, the reference drug may be just as effective as more expensive alternatives, exceptions are permitted where individuals, for medical reasons, require one of the more expensive alternatives. Otherwise, individuals who want the more expensive drugs must pay the difference in price.

The British Columbia drug program estimates that reference drug pricing currently saves it approximately \$30 million annually, and it maintains that this process has not resulted in additional negative health outcomes or increases in non-drug health expenditures. At the conclusion of our audit, there were three different groups of experts conducting research on reference pricing. We were advised that the preliminary conclusion of one of these research groups was that for the category of reference-priced drugs that it had reviewed in British Columbia, expenditures had decreased by \$14.9 million over three-and-a-half years.

Contracting for Drugs

During our audit we also researched drug-purchasing practices in other jurisdictions. In addition to Saskatchewan, which tenders for certain generic drugs and often obtains lower prices than Ontario, the United States Department of Veterans Affairs (VA) also uses a competitive process to obtain certain drugs in its formulary. VA conducted evaluations of classes of drugs to determine whether some or all of the brand-name drugs in a class were assessed as being therapeutically equivalent. Therapeutically equivalent means that the drugs, while differing in chemistry, are judged to be equally safe and effective for most patients. In such cases, VA then decided whether to use a competitive process to obtain some of these drugs. Patients requiring a different drug in a category would be able to get that drug through an exception process.

We selected a sample of the drugs in the VA formulary obtained using a competitive process, including generic drugs and some brand-name drugs that have significant volumes in Ontario, and found that on average, VA's prices were 60% lower than Ontario's. We recognize that it may not be possible for the Ontario Drug Benefit Program to obtain the same prices as the VA. However, the significant differences warrant further examination. For instance, if the Ontario Drug Benefit Program was able to obtain the same prices as the VA for the drugs we selected for comparison, it would have saved at least \$140 million in the 2000/01 fiscal year.

Recommendation

To help ensure that it obtains better value for money for its drug expenditures, the Ministry should assess the costs/benefits of pricing options that have been successfully implemented in other jurisdictions.

Ministry Response

The Ministry has regularly examined and will continue to examine the pricing options used in other jurisdictions. Canada's Patented Medicines Prices Review Board states that prices in Canada are approximately 10% below the median of international prices. In 2000, the prices for patented drugs in Canada were slightly lower than the prices in Sweden, Germany, the United Kingdom, and Switzerland and slightly higher than prices in France and Italy. Ontario's prices compare favorably with those of other provinces.

Written Agreements with Brand-name Drug Manufacturers

One initiative recommended by the Cabinet Committee on Financial Planning to manage drug costs was that brand-name drug manufacturers be required to enter into written agreements with the Ministry. These agreements would require manufacturers to forecast how much a new drug would cost the Ministry in the three years after it is listed in the Formulary. In 1998, a regulation under the *Ontario Drug Benefit Act* required written agreements for all new brand-name drugs added to the Formulary.

In September 1998, the Ministry and manufacturers' representatives signed a Memorandum of Understanding that outlined a process to provide the Ontario Drug Benefit Program with spending predictability. In addition, a Drug Utilization Advisory Committee was established to encourage the appropriate use of prescription drugs, review the utilization of prescription drugs, and identify factors that affect usage. Under this new process, if the use of a drug exceeds what was forecasted in the agreement, the manufacturer has an opportunity to demonstrate that such usage is appropriate—for instance, if the drug is subsequently approved for uses not initially anticipated. However, there was no indication of what action the Ministry can take if the additional use is judged to be inappropriate.

We reviewed a listing of the forecasted amounts in the 113 agreements signed since June 1, 1998 and compared these to actual ministry expenditures for these drugs. We found that in most cases actual expenditures were at least 10% below the forecasted amounts.

In addition, we selected a sample of drugs with actual expenditures either significantly above or below the amounts forecasted in the agreements. In most cases, we were unable to determine how the forecasted amounts in the agreements had been arrived at because these amounts were often significantly higher than the forecasted amounts in the Ministry's supporting documentation.

Where expenditures exceeded the amounts agreed to, branch staff indicated that action was being taken to address the potential overutilization. For example, the amounts in one agreement were being renegotiated, while in another the manufacturer intended to obtain an independent assessment. The Branch indicated that it would be reviewing the scope of the independent assessment to ensure it meets the Branch's requirements.

Recommendation

To help ensure that drug costs are more effectively managed, the Ministry should:

- **evaluate the extent to which the current written agreement process with drug manufacturers is meeting its objectives; and**
- **make improvements as required.**

Ministry Response

The Ministry identified the need for a review of the written agreement process in 2000. The report evaluating the written agreement process has been drafted and a number of recommendations are being assessed.

Health Network System

In 1993, the Ministry issued a request for proposals for the development, installation, and maintenance of a new computerized system for the Ontario Drug Benefit Program. The successful bidder was awarded a five-year, \$86-million contract to develop and maintain the Health Network System (Network).

The Network is an on-line, real-time, claims adjudication, processing, and payment system that links the Ministry and pharmacies. Pharmacists use the Network to claim and receive payment for each prescription they fill for the Ontario Drug Benefit or Trillium Drug program by inputting details regarding the prescription and the eligible recipient, including his or her OHIP number. The Network validates this information using a series of system edits, adjudication rules, and response and intervention codes.

In February 1996, the Management Board of Cabinet issued an Alternative Delivery Framework to assist ministries in determining how to best deliver their services. One approach in the framework was contracting out existing services to the private sector. A ministry would retain ownership, overall responsibility, and control of an activity, but it would employ a private-sector vendor to provide the service. The primary aim of contracting out is to reduce expenditures without reducing the quality of the service.

In 1998, the Ministry, citing the information-technology risks associated with the Year 2000, obtained Management Board of Cabinet approval to extend the Network contract for two years. The extension was approved on the conditions that the total amount paid for seven years' work did not exceed the originally approved \$86 million and the contract was retendered by June 1999.

In January 2000, with Management Board of Cabinet approval, the Branch and its consultants began negotiating a new three-year contract with the vendor. The vendor submitted proposals for both a three- and a five-year contract. After evaluating the proposals, the Branch and its consultants concluded that, from an operational and financial perspective, the five-year contract was preferable. After reviewing the Ministry's analysis, the Management Board approved a five-year, \$63-million contract, which was then signed in September 2000.

The government procurement process, as indicated in the Management Board directives, is to provide a fair, transparent, and open competition to all vendors. Competition among vendors helps ensure that quality services are delivered for the lowest price. If competition among vendors is weak or if a ministry becomes dependent on a single vendor, then the financial and operational benefits of contracting out may be lost.

In reviewing the Ministry's documentation on the Network contracting process, we noted that because the current vendor has gained substantial knowledge and experience, it may inhibit competition for future contracts. This risk is even more significant given that the service being provided has such an impact on the drug programs.

Since there was no competitive selection when the Branch renegotiated its contract for the Health Network System, the Ministry hired consultants to assess the process and ensure fairness in the Branch's review of costs and services. However, the consultants' conclusions were not decisive. For example, one consultant reached the following conclusions: "you appear to have negotiated a fair and reasonable proposal with the vendor" and "the proposed staffing resource counts seem appropriate." This highlights the difficulty in assessing whether untendered contracts represent value for money.

Contrary to Management Board directives, the Ministry did not publicly announce its intent to renegotiate the 2000 contract and had not obtained Management Board approval to do so. Consequently, other potential suppliers may not have been formally aware of the Ministry's intentions. We understand that during the 1998 contract extension process, 17 potential suppliers expressed interest in bidding on the contract.

Recommendation

When selecting a vendor to provide long-term services without using a competitive process, the Ministry should ensure that it:

- receives value for money through respective contracts with such vendors; and
- complies with Management Board of Cabinet directives.

Ministry Response

Prior to the current contract, the Ministry retained external consultants to evaluate the vendor services, and it is satisfied that the opinions obtained from the consultants supported the agreement. The Health Network System is complex and highly customized to meet Ontario's needs, with elements such as eligibility and processing rules. Because the Network has many unique features, the consultants found that no direct comparisons could be made with other systems or contractual arrangements.

The contract with the current vendor is for five years. During this period the Ministry will evaluate the services provided and the options available for future operations and for the maintenance and development of the Health Network System. An extensive evaluation of the Network will be commissioned in the third year of the current contract.

The Ministry will ensure that it is in compliance with all Board directives.

CLAIMS PROCESSING

The Health Network System maintains a number of databases that are used to validate a pharmacy's claim for payment. These databases comprise listings of eligible recipients and approved pharmacies, the Network's processing edits and adjudication rules, and the Formulary. When a pharmacy inputs a claim, the Network verifies the eligibility of the individual and the drug claimed and calculates any deductibles or payments to be made by the recipient. It also checks the prescription for possible drug therapy problems, such as potential drug interactions and duplicate prescriptions.

On a daily basis, information on recipient eligibility is electronically updated on the basis of information from OHIP's Registered Persons Database as well as from the Ministry of Community and Social Services (MCSS) on recipients of social assistance. Changes to the pharmacy database are made based on written notifications from pharmacies, which are confirmed with the Ontario College of Pharmacists.

We reviewed the adequacy of the Ministry of Health and Long-Term Care's procedures for updating its recipient and pharmacy databases and tested a sample of the system's edits. We found that the edits were generally operating as described. However, we also noted the following concerns:

- There was no periodic confirmation with the Ontario College of Pharmacists on the ongoing status of pharmacies. We also found instances where there was no documentation to support the addition or deletion of a pharmacy from the Network.
- A number of records, when checked against the Network's recipients database, which was updated daily, were rejected due to mismatched or missing information, and these cases were outlined in daily exception reports. However, the Ministry did not review or address the cases identified in these exception reports.
- The Ministry did not regularly compare the data in the Network database with MCSS's database to validate data integrity. Missing records or errors might never be noticed or resolved.

Recommendation

To help ensure that pharmacy data within the Health Network System (Network) is complete and accurate, the Ministry should periodically verify pharmacy registrations with the Ontario College of Pharmacists.

To help ensure that only eligible individuals receive benefits through the Ontario Drug Benefit Program, the Ministry should:

- review and follow up on exception reports, which identify mismatched or missing information in the Network's recipients database; and
- regularly compare data in the Ministry of Community and Social Services' database with the Network's database.

Ministry Response

The Ministry's Pharmacy Registration Desk liaises with the Ontario College of Pharmacists (OCP) on a daily basis to verify pharmacy closings and pharmacy ownership information that has been provided directly to the Ministry. The Ministry will continue reviewing ways to enhance verification of OCP registration information, consider making this a mandatory part of the network agreement, and investigate the potential for regular data updates with OCP.

The Ministry carried out a review of exception reports in June, July, and August 2001 and is satisfied that they do not result in errors in claims processing. For the recipient data feed updates, the majority of missing information and/or mismatches did not affect recipient coverage. The Ministry will conduct periodic reviews of exception reports.

The Ministry is working with the Ministry of Community and Social Services to ensure that recipient information is as accurate and up to date as possible.

Temporary Eligibility

Because of delays in updating recipient eligibility files, pharmacists are permitted to establish temporary eligibility for individuals (except seniors) who provide adequate evidence of eligibility, such as a drug card from the Ministry of Community and Social Services (MCSS) or a Home Care Program drug card issued by the Ministry of Health and Long-Term Care. Pharmacies are required to keep copies of the supporting documentation used to assess eligibility for two years. Eligibility is subsequently to be confirmed once the Network receives an update from either MCSS or the Home Care Program.

At our request, the Branch provided data on temporary eligibility granted to social-assistance and home-care recipients during the 1999/2000 fiscal year. The data indicated that pharmacists had provided temporary eligibility to approximately 335,000 recipients during that period. We attempted to quantify the number of these claims that remained unsubstantiated. However, branch staff indicated that, due to system complexities, only a one-percent sample could be provided. We determined that, for that sample, approximately 55% of the claims for temporary eligibility remained unsubstantiated by the Network. Based on the results of this sample, temporary eligibility granted to more than 180,000 recipients remained unsubstantiated.

In 1996, when we recommended that the Ministry of Health and Long-Term Care institute procedures for testing the legitimacy of temporary eligibility, it responded that it was working with MCSS to improve the timeliness and accuracy of its data feed to the Health Network System. During our current audit, branch staff stated that they were still in the process of improving the data feed. This improvement could reduce the frequency of temporary eligibility granted, given that approximately 70% of all temporary eligibility granted in the 1999/2000 fiscal year was related to social-assistance recipients.

Recommendation

To help ensure that temporary eligibility is being granted only where justified, the Ministry should:

- periodically verify the adequacy of supporting documentation maintained by pharmacies where there are significant numbers of unsubstantiated claims; and
- together with the Ministry of Community and Social Services (MCSS), expedite necessary improvements to the MCSS database.

Ministry Response

MCSS maintains and updates the information contained in their database. The Ministry receives regular feeds from MCSS to update the eligibility and personal information contained in the Ministry's Health Network System for MCSS recipients under the Ontario Drug Benefit Program.

A major redevelopment of the MCSS recipient eligibility information system was initiated in 1999. A phase-in of daily update feeds started in May 2001 and will be completed by February 2002. Daily updates will reduce cases of temporary eligibility to exceptional circumstances only. The two ministries are

working together to continue to improve the eligibility data feeds to ensure that recipient eligibility information is accurate and up to date. It is expected that the number of times that a pharmacist has to establish temporary eligibility will be minimal.

The Branch will monitor dispensaries that have a higher-than-average number of claims for recipients for whom temporary eligibility was established.

Warning and Information Messages

When a pharmacist inputs a prescription into a computer linked to the Health Network System, the Network uses information about the new prescription and the individual's previous prescriptions to identify potential drug therapy problems, such as possibly serious drug interactions or duplicate prescriptions. When the Network identifies potentially serious problems, it rejects the prescription for payment and sends a warning to the pharmacy that is displayed on the pharmacist's computer. For less serious problems, such as prescriptions being filled too soon after a previous prescription, the Network accepts the prescription but sends an information message about the problem to the pharmacist.

In cases where prescriptions have been rejected, the pharmacist may resubmit the claim with an appropriate intervention code that indicates the action that has been taken to resolve the issue identified by the warning. For example, the pharmacist might indicate that the prescriber was consulted to ensure that the prescription should still be filled.

According to ministry statistics, in the 2000/01 fiscal year, the Network sent 1.6 million warnings to pharmacists that related to serious drug interactions. In 90% of these cases, pharmacists resubmitted the claim, and the prescription was processed. In most of these cases, pharmacists indicated that they had determined the prescription was appropriate. However, without conducting a proper evaluation, the Ministry cannot determine whether certain warning messages should be revised.

Also during the 2000/01 fiscal year, the Network sent pharmacies 20 million information messages that identified less serious drug interactions and other potential drug therapy problems, such as patients obtaining the same prescription from more than one doctor. In 5% of these cases, prescriptions were not filled and the claim was reversed by the pharmacist. The specific reasons for the reversals of these claims cannot be determined because pharmacists are not required to submit an explanation. In fact, explanations were only submitted for 30 of the claims that were reversed. Without a proper evaluation, the Ministry cannot assess the impact of the information messages sent to pharmacists.

In our 1996 audit, we recommended that the Ministry assess whether the intended benefits of the Health Network System had been realized. At that time, the Ministry responded that it intended to enhance the Network's ability to identify potential drug therapy problems.

Though the Network currently identifies drug interactions, it does not perform a therapeutic duplication check to determine whether a prescription contains ingredients in the same therapeutic class as other drugs prescribed to an individual. The intent of such a check would be to avoid adding a new drug where it may lead to too strong an effect. This check would be especially useful when the patient is consulting more than one prescriber. Where pharmacists in

other jurisdictions have been surveyed about this matter, they have rated therapeutic duplication checks as being almost as useful as information about drug interactions. A survey in one jurisdiction found that most pharmacists agreed that their system's therapeutic duplication check identified problems that would otherwise go unnoticed.

Recommendation

To improve the effectiveness of the Health Network System's warnings and information messages, the Ministry should assess whether:

- **the existing warning and information messages need to be revised; and**
- **other potential drug therapy problems, such as a therapeutic duplication check, should be added to the Network.**

Ministry Response

The Health Network System uses Drug Use Review tables developed by an external service provider. These are the tables most commonly used for drug interactions and warnings. The tables now in place in the Network are the most up-to-date versions available on the market and include a check on therapeutic ingredients and therapeutic duplication that identifies drugs in the same therapeutic class.

The Drug Use Review tables are a standardized system that helps pharmacists identify potential drug-related problems. Pharmacists decide what action is required within their scope and standards of practice.

The Ministry will investigate whether additional modules are available and necessary.

SYSTEM SECURITY

System security guidelines and procedures generally outline the security aspects of a computer system and cover such areas as: the accountability and responsibility of management and of security and user groups; access administration (including the set-up, modification, and deletion of user accounts); and security monitoring.

In March 1998, Management Board Secretariat issued a Directive on Information and Information Technology Security. The Directive stated that the security measures within a ministry must be co-ordinated by "a senior executive who is responsible for information and information technology security." At the time of our audit, we noted that no senior executive responsible for security had been appointed for the Health Network System. In addition, documentation of ministry security procedures was not up to date, and the private-sector service provider was still developing security-related procedures to administer the Network. By the end of our audit, the service provider had not yet set a completion date for the development of the procedures.

During our audit, we identified a number of areas where security for the Network required improvement. For instance, all users of the Network are to be assigned to user groups. For each

user group, a business case is required to determine the standardized functions these users may perform and the data they may access. The Ministry was unable to provide supporting documentation for 10% of the user groups we reviewed, and, accordingly, we were unable to determine whether the system access assigned to those user groups was appropriate.

We found that two user groups had system access privileges that would allow them to both set up pharmacy accounts, including banking information, and process claims. Setting up accounts and processing claims should normally be segregated to help reduce the risk of false claims being processed.

According to the Ministry's security procedures, access to the Network requires approval from the Ministry's network security administrator. Any system access changes should be documented and properly approved before being processed by the service provider. At the time of our audit, we noted the following:

- A few users obtained system access or their access privileges were modified by the network service provider without the proper requests and authorization from the Ministry. As a result, system access privileges might have been inappropriately assigned, and the Ministry's security administrator was unable to perform regular access reviews.
- The service provider set up new user accounts and provided the passwords to individuals besides the users. In our opinion, these individuals did not require these passwords to perform the tasks and responsibilities assigned to them.
- The security administrator was not notified to terminate system access when users left their job function.

We also found that the protection of data and system files could be improved. For instance, service provider employees who had privileged system access allowed their files to be modified by other staff members, potentially exposing the system and data files to unauthorized viewing and modification. The service provider also did not adequately track which individuals had system access. We found cases where user identifications had been issued without a defined owner.

Monitoring is an important detective control for identifying security breaches and abuse of privileges. We noted that the Ministry was still in the process of developing procedures for monitoring security.

Recommendation

To help safeguard information in the Health Network System against unauthorized use, disclosure, modification, damage, or loss, the Ministry should:

- **assign the responsibility for the Network's security to an appropriate senior manager;**
- **ensure appropriate security policies and procedures are in place;**
- **review staff duties to ensure that system access is appropriate;**
- **implement more rigorous controls over the access administration process and system protection; and**
- **ensure that the Network's security is actively monitored.**

Ministry Response

The responsibility for the Network's security has been formally assigned to a senior manager in the Branch, and there is a clear delineation of roles in approvals on security-related matters.

Formalized Health Network System security provisions are in place and are documented. In keeping with the terms of the existing contract with the vendor, security protocols are regularly reviewed to ensure that appropriate security policies and processes are in place and that system access is appropriate.

The Ministry has initiated meetings with the service provider and the Human Services Cluster security group to review the security procedures and to address the above recommendations. Where warranted, enhanced security procedures will be implemented in winter 2002. It is a priority of the Ministry to compile all security procedures into a single document as part of this review.

The communications network meets current industry standards for security. The current communications network is scheduled for replacement by April 2003. The replacement network will meet all the security standards established by the Smart Systems for Health.

The security administrator or the security administrator's immediate supervisor grants access approvals. The Ministry will ensure that, during the review of the security procedures, it is clarified that both positions are authorized to approve system access requests.

The Ministry acknowledges that there were a few isolated incidents in the past where the service provider's technical staff did not have access approval from the system administrator. The Ministry is satisfied that no inappropriate access was granted, and such procedures have been tightened.

In terms of notifying the system administrator when people leave their job, the Ministry took immediate action on the identified users to remove their access in March 2001. Currently, the onus is on individual branch managers to notify the system administrator of staff changes. Notification of staff changes to the system administrator will be included in the above-noted security review.

Contract Management

A key requirement of an Alternative Service Delivery model is the development of a contract management function to effectively monitor the performance of the vendor regarding the contract terms and to take timely corrective action when required.

During the course of our audit, we reviewed contract management for two areas—the Health Network System and the seniors reduced co-payment.

HEALTH NETWORK SYSTEM CONTRACT

In December 2000, the Ministry engaged consultants to review the Branch's contract management practices relating to the Health Network System contract. In their March 2001 report, the consultants identified a number of opportunities for improvement that centred on the need to monitor adherence to contract terms by the Branch and the vendor. The consultants' recommendations included:

- the creation of a core group of staff, led by a Contract Manager;
- the development of a succession plan in case key system and program staff leave the Ministry; and
- the development of a strategic plan to address future hardware replacement and program/policy changes, including the potential transfer of service delivery to another vendor.

The consultants concluded that the Branch would have to assess these opportunities for improvement and determine which ones would have the greatest impact, and then establish an implementation plan. Branch staff advised us that the Ministry had reviewed the consultants' report and was in the process of considering the recommendations.

SENIORS REDUCED CO-PAYMENT CONTRACT

Since July 1996, recipients of Ontario Drug Program benefits have been required to pay a portion of their prescription drug costs. The amount of the contribution is based on the recipient's income. All residents of long-term care facilities, individuals receiving home care, and seniors with incomes below certain thresholds receive a reduction in the amount of their co-payments.

To receive a reduction in the amount payable, seniors must show evidence of their income through an application process. Since 1996, a private-sector vendor was competitively selected and awarded contracts to administer this process.

The Ministry did not have procedures in place to verify processing accuracy, which is critical in ensuring recipients pay the correct amount towards their prescription drug costs. At the time of our audit, the Branch had not reviewed the accuracy of the vendor's procedures for approving applications and issuing refunds, nor had it assessed whether the minimum performance standards in the contract had been met. Standards included, for example, the time taken to process applications and receipts. While branch staff indicated to us that the vendor conducts periodic quality-assurance reviews of its activities, at the time of our audit the Branch had not received reports on the type of reviews conducted or the results.

Recommendation

To enhance accountability, the Ministry should ensure that it has adequate policies and procedures in place to monitor whether contracted services are carried out in accordance with the terms, conditions, and performance standards set out in contracts.

Ministry Response

Under the new contract, effective May 1, 2001 payment for contracted services is based on “cost per unit of work performed”—that is, the cost of a work unit such as the processing of an application or receipt or the handling of a telephone call. This unit cost of work includes all administrative and business costs for the service provider. No separate payment is made for staffing. The Branch is working with the Ministry’s internal audit branch to implement procedures for periodic reviews during the term of the new contract.

Inspections and Verification

At the end of our current audit, the Branch had five inspectors in its Inspection Unit reporting to a manager who, in addition to other responsibilities, supervised the inspectors. The primary responsibility of the Unit is to ensure that the claims paid by the Ontario Drug Benefit and Trillium Drug programs are valid. Where fraud is suspected, the case is referred to the Ministry’s Investigation Unit. During the 2000/01 fiscal year, the Inspection Unit completed approximately 110 inspections, identifying \$575,000 in recoveries and referring two cases to the Investigation Unit.

INSPECTION RESOURCES

In our 1996 audit report, we recommended that, to ensure that pharmacies are inspected on a timely basis, the Ministry should implement a system for prioritizing and scheduling inspections, including an annual inspection plan approved by management. The Ministry responded that it was developing a Pharmaceutical Audit System as part of an enhancement of the Health Network as well as an annual inspection plan. The Pharmaceutical Audit System would assist in setting priorities and scheduling inspections, and it would maintain a record of a pharmacy’s last inspection and the outcome.

In its 1996/97 Annual Report, the Standing Committee on Public Accounts made the following recommendation:

the Ministry has said that the Pharmaceutical Audit System should be fully implemented by September 30, 1997. The Committee should be provided with a detailed accounting of the ways in which the system will respond to the Provincial Auditor’s recommendations regarding the inspection process, along with an analysis of the impact on inspection resources and potential changes to legislation.

In February 1998, the initial phase of the Pharmaceutical Audit System was implemented. However, inspectors whom we interviewed during our current audit indicated that the Pharmaceutical Audit System did not meet their needs. For example, the system was unable to generate sufficient samples where there were large volumes of claims.

In addition, we noted there was no annual inspection plan for the 2000/01 fiscal year. Some inspectors had submitted plans in the previous year but had not indicated which pharmacies they planned to inspect. While annual inspection plans must be able to accommodate changes in priorities, such as those caused by findings or complaints, the plans should be reviewed and approved by management to help ensure that inspection resources are appropriately allocated. Plans should indicate the pharmacies selected for inspection and the reasons for selection.

Adequate policies, procedures, and information systems help ensure that inspections are conducted properly and efficiently. Management review provides assurance that the policies and procedures are being adhered to. In 1996, we noted that the Branch did not have formal policies or procedures for conducting inspections. In response, the Ministry stated that a draft manual of inspection policy and procedures was being developed. At the time of our current audit, the manual was still in draft form and did not address certain concerns identified in our previous audit. For instance, based on discussions with inspectors and a review of a sample of inspection files, we found that documentation was insufficient to determine whether required standard procedures were performed. Furthermore, the standard inspection reports we reviewed were insufficient for management to determine which procedures had been performed. We also noted that the time periods over which recoveries were calculated was not always consistent.

Recommendation

To help ensure that inspection resources are used efficiently and effectively, the Ministry should:

- **implement needed improvements to the Pharmaceutical Audit System to facilitate the work of inspectors;**
- **ensure inspection plans are prepared and approved by branch management;**
- **provide for sufficient management review of the work of inspectors; and**
- **review the adequacy of the policies and procedures in the draft manual.**

Ministry Response

Phase II of the Pharmaceutical Audit System of the Health Network System will be implemented in June 2002.

Inspection plans, approved by branch management, will be in place by the end of October 2001.

Management's review of inspections has been formalized. The policies and procedures manual will be reviewed, and suggested recommendations will be considered. The manual will be finalized by February 2002.

INSPECTION COVERAGE

At the end of our 1996 audit, we noted that one of the five inspector positions in the Branch was vacant. At that time, we were informed that approval had been obtained to fill the position. However, this position remained vacant until October 30, 2000. Branch management informed us that, during the more than four years that the position was vacant, the only inspections conducted in the affected territory were as a result of complaints—even though this territory accounted for approximately 20% of annual ministry expenditures for the Ontario Drug Benefit and Trillium Drug programs.

As of April 2001, over 3,300 dispensing agencies, including approximately 2,700 retail pharmacies, were operating in Ontario. Branch management estimated that most agencies were only being inspected once every 10 years. This means that most billings would not be inspected since routine inspections only cover the previous two years. In addition, in some instances, more time-consuming, in-depth inspections are required. The Branch has not assessed how frequently agencies should be inspected.

Given the inspection resources available, we were informed that inspectors focused their efforts on pharmacies judged to be potentially at high risk for fraud or error. We recognize that many factors enter into determining which pharmacies are high risk. We requested a report of pharmacies whose billings suggested they might be high risk and obtained information about pharmacists who had been disciplined by the College of Pharmacists for offences suggesting a lack of integrity. Based on our review, we concluded that there were a number of agencies that should have been inspected but were not. Branch management indicated that they planned to inspect some of them in the next year. The timeliness of the inspection of high-risk pharmacies is an important consideration when assessing whether the available inspection resources are adequate.

Inspections, in conjunction with similar activities such as verification letters, need to be sufficient in order to detect significant billing errors and create a “sentinel effect,” whereby it is known that pharmacies put themselves at significant risk of detection if they process false claims.

Recommendation

To minimize the risk of paying for invalid claims, the Ministry should ensure that sufficient resources are assigned for the inspection of pharmacies.

Ministry Response

The Ministry has a policy of zero tolerance on fraud and reports all cases of suspected fraud to the Ministry’s Fraud Unit.

The Ministry has reviewed and will continue to review inspection activities in other provinces and jurisdictions to determine the most effective method of identifying and inspecting high-risk pharmacies.

The Ministry will review the resources in place to inspect pharmacies.

VERIFICATION LETTERS

In our 1991 and 1996 audit reports, we stressed the importance of having adequate procedures to verify, on a test basis, the validity of the claims the Ministry was paying. In 1996, the Ministry stated that an enhancement planned for the Pharmaceutical Audit System would allow for a random selection of claims to be verified. During our current audit, we found that this had still not been done. In fact, as was the case when we conducted our audit in 1996, verification letters were only being sent to prescribers and recipients to verify the billings of pharmacies where false claims were suspected. For instance, in 2000, a total of 570 verification letters were sent to prescribers and patients as part of the inspections of two pharmacies.

As part of our current audit, we obtained information on the verification processes used by drug plans in British Columbia, Florida, and the state of New York. We found that all three routinely sent verification letters to recipients to confirm that prescriptions billed by pharmacists were actually received by the patient. For example, the province of British Columbia indicated that it annually sent out approximately 18,000 randomly selected verification letters. Drug plans in Florida and New York had similar processes whereby claims for verification were selected randomly based on risk assessments.

For some other ministry-administered programs in Ontario, such as OHIP, the Ministry sends random verification letters to patients to confirm the receipt of services. Furthermore, in April 2001, as part of its initiative to increase the accountability of the broader public sector, the government indicated that it would be developing itemized statements to send to patients to confirm that services billed to OHIP on their behalf were actually provided. Verification letters can be an efficient way of ensuring that drugs paid for by the Ontario Drug Benefit and Trillium Drug programs have been received. With adequate follow-up they can act as a significant deterrent to the processing of false claims.

Recommendation

To help ensure that the drug programs pay only for valid prescription claims submitted by pharmacists, the Ministry should implement adequate procedures to verify claims with recipients.

Ministry Response

At the discretion of the pharmacy liaison officer, verification letters may be issued to recipients and prescribers during a dispensary audit. In addition, information verification letters are issued to pharmacies by the help desk of the Health Network System requesting detailed information to support specific claims paid under the Ontario Drug Benefit Program.

The Branch will review the audit activities in other provinces and will work with the Anti-Fraud Branch and Audit Branch to ensure that its audit functions and resources are adequate.

VERIFICATION OF LIMITED-USE DRUG FORMS

In May 1996, the *Ontario Drug Benefit Act* was amended to add certain designated drugs to the Formulary that would be covered only if specified clinical criteria were met. Prior to that date, these limited-use drugs were not listed on the Formulary and required separate approval for funding.

In May and July 1996, pharmacists were reminded that claims for limited-use drugs were only eligible for payment when the criteria were met and supported by the appropriate, valid, properly completed, limited-use drug form signed by the prescriber. Pharmacists were advised that, in cases of non-compliance, amounts paid would be recovered.

In January 1997, the Branch requested that approximately 2,500 pharmacies provide supporting documentation for approximately 10% of the limited-use claims submitted between May and December 1996. Approximately 1,900 pharmacies did not provide adequate supporting documentation to validate their claims. As a result of this audit, the Ministry estimated that approximately \$4.5 million was recoverable from these pharmacies.

In October 1997, ministry staff met with representatives of the Ontario Pharmacists' Association to discuss the Association's concerns with the results of the audit. Ministry officials agreed to permit pharmacists to produce additional documentation to support the appropriateness of their claims. In November 1997, the Association's representatives met with the Minister, and there was agreement to defer recoveries until after the Ministry and the Association had held discussions about other initiatives. While these discussions were apparently completed in late 1998, no action was taken by the Ministry to begin recoveries.

In December 1998, the Ministry introduced new limited-use forms, and the criteria for some limited-use drugs were changed. Physicians and pharmacists were reminded that the new requirements would be enforced.

In June 2000, program staff informed senior ministry management of a plan to initiate recoveries identified by the 1997 audit. However, program staff believed it impossible to recover payments in cases where limited-use forms had invalid criteria, because pharmacists were not required to keep supporting documentation for more than two years. In January 2001, ministry staff estimated that this would reduce the amount to be recovered to \$1.5 million—mainly representing instances where no form was provided to validate the claim or where the form had expired.

In early 2001, the Association was advised in writing “that the Ministry will not require any recovery of funds from the Limited Use Audit carried out in 1997. The Ministry considers this matter closed.” However, we found that the Ministry had not followed the established processes that would permit it to forego the recovery of these funds under the terms of the *Financial Administration Act*.

Recommendation

To help ensure that the costs of limited-use drugs are only covered where warranted, the Ministry should:

- ensure that adequate procedures are in place to periodically verify that limited-use claims are supported by valid documentation; and
- enforce recoveries where pharmacists do not provide adequate evidence that limited-use drug criteria have been met.

Ministry Response

The Ministry is in the process of following the established processes and terms of the Financial Administration Act for recoveries in its limited-use audit to ensure appropriate accounting treatment with respect to write-off procedures.

The substantiation of limited-use claims is part of routine site inspections of pharmacies, and recoveries are instituted on all claims without appropriate documentation.

The Ministry plans to carry out periodic office audits of limited-use claims in the future, and recoveries will be made where claims are not supported by valid documentation.

TRILLIUM DRUG PROGRAM

The Trillium Drug Program was introduced in 1995 to provide financial assistance to individuals and families with high annual drug costs in relation to their incomes. To qualify for benefits, each individual or family must annually submit an application along with proof of income and any private insurance coverage. The Program covers all prescription drugs listed as benefits in the Ontario Drug Benefit Formulary. For the 2000/01 fiscal year, the Ministry's expenditures for the Trillium Drug Program totalled \$77 million.

Recipient Deductibles

The Trillium Drug Program requires that applicants pay a deductible based on the household's annual net income and number of dependents. The annual deductible is the dollar value the recipient or household must spend on prescription drugs covered by the Program before becoming eligible to receive benefits from the Program. Currently, the deductible represents approximately 4% of a household's net income.

Since 1999, the annual deductible has been payable in quarterly instalments. Recipients who incur drug costs in excess of the quarterly instalment are then eligible for program benefits in that quarter. Recipients are required to pay \$2.00 for each prescription processed after their deductible has been reached. In cases where a recipient does not pay the full amount of a quarterly instalment (because their drug costs do not exceed the deductible in that quarter), the unpaid portion is to be added to the next quarter's instalment.

We found that in implementing the quarterly instalments, the Branch did not adequately address the possibility that recipients could be eligible for benefits while not meeting their annual deductible amounts. For example, a family could receive substantial assistance and only pay one quarter of its deductible if all drug purchases were made during that quarter. A report prepared by the Branch for the 1999/2000 benefit year indicated that, for approximately 5,000 families who received a total of \$3.7 million in benefits, approximately \$750,000 in deductibles had not been applied against drug costs for that year. This occurred primarily because recipients were eligible for benefits in one or more, but not all four, quarters. The Ministry does not have a process in place for recovering deductibles that were not paid in these circumstances.

Recommendation

To better ensure that Trillium Drug Program benefits are provided in accordance with the intent of the Program, the Ministry should develop policies and procedures to:

- reduce or eliminate underpayments of the deductible; and
- recover any underpaid deductibles.

Ministry Response

The Ministry will institute a review of the computerized application of the quarterly deductible and will examine options for reducing or eliminating underpayments of the deductible and options for recovery.

SPECIAL DRUGS PROGRAM

The Special Drugs Program was introduced in 1986 to cover the cost of prescription drugs required for the treatment of specific health conditions, such as HIV and end-stage renal disease. To be eligible for coverage, an individual must be an Ontario resident, have a valid health insurance number, meet the clinical criteria, and have one of the conditions covered by the Program.

At the time of our current audit, there were 11 prescription drugs funded by the Program. Since 1993, new drugs that treat conditions covered under the Special Drugs Program, such as anti-rejection drugs for transplants, are added to the Formulary and are covered by the Ontario Drug Benefit or Trillium Drug programs. For the 2000/01 fiscal year, the Ministry's expenditures for the Special Drugs Program totalled \$107 million.

Regulations under the *Ontario Health Insurance Act* provide the funding authority for special drugs and their corresponding conditions. Unlike the Ontario Drug Benefit and Trillium Drug programs, the Special Drugs Program does not require the payment of a deductible or co-payment for drugs provided. Instead, patients obtain these drugs free of charge on an outpatient basis from an authorized facility—usually a hospital—that the Ministry has designated to distribute the drugs.

In our *1996 Annual Report*, we recommended that the Ministry consider whether the Special Drugs Program was needed in its current form, given that the Trillium Drug Program covers people with high drug costs relative to their incomes, and, if it was needed, determine whether it was consistent with the Ontario Drug Benefit Program's objective of providing equitable protection. At that time, the Ministry agreed that consideration should be given to the consistency of the application of the objective of equitable protection. It also indicated that it would be reviewing the three programs to consider the possibility of redesigning their various components to ensure consistency and compatibility.

In January 1999, the Branch engaged a consultant to develop a plan to include the Special Drugs Program on the Health Network System. Initially, two drugs representing 67% of the expenditures of the Special Drugs Program were to be added to the Health Network System, and reimbursement would be managed in a way that was similar to that of the Ontario Drug

Benefit and Trillium Drug programs. The consultant noted that this would enable the Branch to ascertain:

- the names of the prescriber, the recipient, and the authorizing hospital; and
- the name of the pharmacist who assesses the recipient's eligibility by confirming the recipient is an outpatient who is an Ontario resident, has a valid OHIP number, and has a medical condition that is covered by the Program.

This information would enable the Branch to check for potential drug interactions and duplicate prescriptions, as well as monitor drug use and trends. To date, no action has been taken with respect to the consultant's report.

Recommendation

The Ministry should consider whether the Special Drugs Program is needed in its current form and whether the administration of the Program could be integrated with the Ontario Drug Benefit and Trillium Drug programs.

Ministry Response

The Ministry will continue to review the Special Drugs Program and make recommendations to government on future action, as deemed appropriate.

Payment Processing

Hospitals that distribute drugs covered by the Special Drugs Program obtain these drugs directly from the manufacturer. The cost of the drugs is often determined through contracts between the Ministry, the hospital, and the manufacturer. Hospitals forward the invoices they have paid to the Branch for reimbursement. We reviewed the procedures used by the Branch to pay invoices submitted by hospitals and found the following:

- Based on a review of contracts and a sample of hospital invoices, for one drug product, hospitals had paid and were reimbursed by the Ministry at a higher price than in the contract. At our request, branch staff reviewed all the invoices for that drug for the past five years. As a result, the Branch was in the process of recovering approximately \$475,000 from the manufacturer.
- The Branch continued to pay a hospital \$465,000 annually for administrative costs related to the distribution of drugs to other hospitals, even though its contract with the hospital had expired in 1996. As well, the Branch did not require the hospital to submit a budget for administrative costs.
- The Branch did not collect sufficient statistical information to monitor the reasonableness of the volume of drugs paid for by the Program. While the price of drugs covered has remained relatively constant, according to the Branch's statistics, total expenditures for some drugs have risen significantly. However, since the Branch did not have adequate information on the

number of patients receiving the drugs, it could not assess whether such increases were reasonable.

Recommendation

To help ensure that payments from the Special Drugs Program are reasonable, the Ministry should:

- **establish procedures to compare invoiced amounts to prices in contracts between hospitals and manufacturers;**
- **ensure any administrative costs being paid to a hospital are justified; and**
- **monitor the volume of drugs paid for by the Program.**

Ministry Response

All invoices for payment of drugs under the Special Drugs Program must contain the price per unit, and this is compared to the prices agreed to in the relevant contract. The contract prices are being enforced.

The Ministry's review of the Special Drugs Program will include a review of administrative and accountability procedures.

Recoveries from the manufacturer are being made and will be completed by March 31, 2002.

PERFORMANCE MEASUREMENT AND REPORTING

The mission of the Drug Programs Branch is: "to provide leadership in achieving optimal pharmaceutical services for the protection and improvement of the health status of the residents of Ontario." To achieve its mission, the Branch has identified several objectives, including:

- achieving equitable protection for Ontarians from unaffordable prescription drug costs; and
- containing costs with suitable controls to keep Ontario's prescription drug programs affordable.

The Branch has developed performance measures for some of its objectives. For example, the Branch had developed workload targets and standards for processing Trillium Drug Program applications and receipts. During our audit, however, we found that the Branch had not developed a complete set of measures for its activities, and no report was available for senior ministry management to enable them to assess how well the Branch was meeting its objectives.

Effective accountability requires that the public and the Legislature receive adequate and timely information about the performance of a program. Our review of the Ministry's 2001/02 published Business Plan found that it provided no financial information or measures of performance for the drug benefit programs, which are very large and fast-growing health programs. For example, information on the results of drug program initiatives to manage costs were not available. We

noted that some jurisdictions were attempting to measure the performance of their drug programs and were making annual reports available to the public and other interested stakeholders.

Recommendation

To provide better accountability to the public and the Legislature, the Ministry should develop a comprehensive set of performance measures and report regularly and publicly on the performance of the drug benefit programs.

Ministry Response

Information will be released annually on drug program activities and a report on 2000/01 activities will be posted on the Ministry's Web site in the near future.

The Ministry will consider additional performance measures for the program.