# Chapter 4 Section 4.05

Ministry of Health and Long-Term Care

# **Drug Programs Activity**

Follow-up on VFM Section 3.05, 2007 Annual Report

## **Background**

Ontario has a number of drug programs that provide prescription drugs to Ontario seniors, social assistance recipients supported by the Ontario Works and Ontario Disability Support programs, and certain other types of eligible recipients as defined under legislation. The Ministry of Health and Long-Term Care (Ministry), through the Health Network System (Network), processes payment of drug claims, and provides on-line information to pharmacists. The Network is linked to approximately 3,050 pharmacies and 100 other dispensers.

The Network processes 109 million prescriptions annually for approximately 3.2 million eligible recipients. For the 2008/09 fiscal year, total expenditures for Ontario's drug programs were \$4.1 billion (\$3.7 billion in 2006/07), of which \$774 million(\$742 million in 2006/07) was paid by the Ministry of Community and Social Services for drug benefits for social assistance recipients.

Our 2007 audit indicated that the externally managed Network generally processed drug claims in accordance with legislative requirements and ministry policy. However, to further control costs, the Ministry must be more vigilant in ensuring that the risks related to ineligible claimants and unusual drug claim patterns are appropriately addressed. Specifically:

- The Ministry did not closely monitor pharmacists' use of system override codes to grant drug coverage eligibility to recipients identified by the system as ineligible for drug coverage. System overrides must be supported by appropriate documentation such as temporary eligibility cards. For instance, one pharmacy made more than 300 claims in a five-month period through system overrides for one individual who was ineligible for drug coverage during that time.
- When pharmacists acquire drugs at costs greater than the Ontario Drug Formulary (Formulary) prices, they can be paid at these higher drug prices by entering a price override code in the system. Our review of a sample of price override claims paid by the Ministry in February 2007 found that more than 30% of the unit drug prices in these claims exceeded their Formulary prices by more than 100%. In one case, the price claimed exceeded the Formulary price by 12,500%, resulting in the Ministry paying almost \$2,400 for a claim that, according to the Formulary price, should have cost less than \$20.
- Our previous audits in 1996 and 2001 and the Standing Committee on Public Accounts all expressed concern about the decline in field inspections of pharmacies. Our work in 2007 indicated that, at the Ministry's current inspection rate of 3% of dispensing agencies in a year, it will take up to 30 years to cover all

agencies. The Ministry needs to target highrisk dispensing agencies identified through activities such as a review of unusual claims statistics. For instance, our review of 2005/06 claims data found that 20 dispensing agencies filled prescriptions for an average drug supply of less than three days, which allowed them to charge more dispensing fees, yet only one of these agencies was inspected in the last six years. In conjunction with the Ministry, we selected a dispensing agency that had a high number of claims per drug recipient and attended the related field inspection. This single inspection identified \$270,000 in overpayments, of which \$240,000 was because of claims for invalid dispensing fees.

We made a number of recommendations for improvement and received commitments from the Ministry that it would take action to address our concerns.

### **Status of Recommendations**

The Ministry has made good progress in addressing most of our recommendations, although several will take another year or two to be fully addressed. The status of the actions taken on each recommendation at the time of our follow-up is as follows.

#### **ELIGIBILITY FOR DRUG COVERAGE**

#### Recommendation 1

To ensure that only eligible recipients receive or continue to receive drug coverage, the Ministry of Health and Long-Term Care (Ministry) should ensure that:

- income levels of seniors receiving reduced co-payments are supported by proper documentation or through electronic means, such as the Canada Revenue Agency income link;
- eligibility override codes used by pharmacists are applied and supported appropriately;

- the use of override codes is monitored and abnormally high override rates are investigated; and
- continuing eligibility of long-term-care residents is confirmed independently by obtaining information from the long-term-care homes or the Ministry's Long-Term Care Program.

#### **Status**

The Ministry advised us that the electronic link to Canada Revenue Agency (CRA) income information for the Trillium Drug Program is in place; the Ministry was in the process of enhancing this link at the time of our follow-up and expected it to be complete by the end of the 2009/10 fiscal year. Once enhancement is completed, the Ministry will determine what systems and program-administration changes are required to implement electronic income verification through the CRA for the Seniors' Co-payment Program. Seniors applying for the Seniors' Co-payment Program are to provide proof of income and a signed consent form, and the Ministry is to verify their eligibility for benefits using the CRA link when this feature becomes available.

The Ministry informed us that because the use of override codes was specific to the situation and the clinical decision of the pharmacist who initiated the code, it did not set benchmarks for the use of these codes. Instead, the Ministry's inspection staff had been ensuring compliance by reviewing claims and monitoring any abnormal activity relating to the use of an override code, and investigating where appropriate. In their reviews, inspection staff had been considering the clinical expertise of pharmacists who had decided to use the code and requesting documentation to support any claims submission.

Because there is no data repository of longterm-care residents in the Ministry's Long-Term Care Program, the Ministry had not been able to use internal information to verify the continuing eligibility of these residents. To support its audit function, the Ministry had doubled its inspection resources for doing site-inspections and auditing claims submitted by pharmacies. Where applicable, the Ministry would check with long-term-care homes to verify the eligibility of residents.

#### PROCESSING OF PAYMENT CLAIMS

#### **Electronic Processing of Payment Claims**

#### Recommendation 2

To help ensure that all claims are processed accurately and completely in accordance with legislative and policy requirements, the Ministry of Health and Long-Term Care should:

- periodically perform Health Network System (Network) assessments or tests to identify areas of non-compliance, with particular emphasis on ensuring that the Network has been updated for program changes; and
- regularly obtain information from the Ontario College of Pharmacists (College) on pharmacy closings to update the Network database.

#### **Status**

The Ministry cited the following initiatives it had put in place to identify areas requiring updates to the Network since our 2007 audit:

- In 2008, the Ministry instituted a governance process for information technology changes to the drug program portfolio. Specifically, a team of senior managers from the business, policy, and information technology areas relating to drug programs were meeting monthly to prioritize projects and to monitor the status of projects under way and assess the impact of any proposed policy changes on the Network.
- In 2008, the Ministry terminated all prior agreements and entered into a new agreement with all the dispensing agencies in the Network. This new agreement reinforced to dispensing agencies that claims must be submitted in compliance with the Ministry's legislative and policy requirements and provides the Ministry with clearer authority to terminate agreements.

- The Ministry completed a review of adjudication rules for recipients under the Ontario Works drug program. As a result of this review, the Ministry updated the information in the Network in February 2009 to allow a maximum 35-day supply of drugs for recipients in the Ontario Works program even if they are also registered in the Trillium Drug Program (some recipients had been receiving up to a 100-day supply of medication).
- In 2008, subsequent to a review of claims data on the frequency of dispensing in the Ontario Drug Benefit Program, legislative changes were made such that the Ministry would pay a maximum of two dispensing fees to dispensers for the supply of a listed drug product in a calendar month. The Ministry believes that these changes will result in substantial savings.

The Ministry informed us that the Ontario College of Pharmacists regularly notified it of new pharmacy openings and changes of ownership. In addition, the Ministry told us that it had updated the Network and reconciled pharmacy listings in 2008 and early 2009.

#### **Cost-to-operator Payments**

#### Recommendation 3

To ensure that it pays drug prices charged in excess of Formulary prices only when appropriate, the Ministry of Health and Long-Term Care should:

- regularly review and monitor pharmacy claims for manufacturer costs exceeding Formulary prices for accuracy and for evidence of manufacturer invoice support; and
- take appropriate action to recover overpayments when claims are found to be invalid or incorrect and when drug manufacturers are in non-compliance with Formulary prices.

#### **Status**

The Ministry informed us that it had reviewed all Formulary products to ensure that information was current and accurate and that some 300

discontinued products had been removed. The Ministry estimates that this will result in savings that could average several million dollars annually. The Ministry had also recovered overpayments of \$2.3 million between January 2008 and June 2009, an 18-month period, which it found during routine audits that identified discrepancies in claims. As of June 2007, the Ministry no longer allows the use of cost-to-operator intervention codes for almost all generic drugs, as well as for brand-name drugs with price agreements and no equivalent interchangeable products (at the time of this follow-up, approximately 60% of brand-name drugs fell into this latter category). Blocking the use of such codes prevents pharmacies from charging more than the drug-benefit price that is listed in the Formulary.

The Ministry informed us that it was allowing the use of intervention codes for brand-name drugs that are without price agreements but that legislation requires that a manufacturer supplying a listed drug product for the purposes of the public drug program must sell it at the drug-benefit price listed in the Formulary. Regarding claims for single-source drugs, which are typically brand-name products, the Ministry informed us that the Network was not paying dispensers an amount higher than the drug-benefit price.

## Manual Processing of Paper Claims and Reimbursement Receipts

#### Recommendation 4

To ensure that all manual claims are valid and are accurately processed in compliance with legislative and policy requirements, the Ministry of Health and Long-Term Care should conduct regular quality-assurance reviews of such claims.

#### Status

The Ministry informed us that it had implemented a quality-assurance process in April 2007, and had since made adjustments to, and continued to review, this process. As part of its quality-assurance process, the Ministry was completing random

checks of approximately 10% of claims on a weekly basis. The Ministry was correcting errors identified through these checks and using them in its refresher training where possible.

#### **INDIVIDUAL CLINICAL REVIEWS**

#### **Recommendation 5**

To more effectively identify high-request drugs for inclusion in the Formulary, the Ministry of Health and Long-Term Care should consider tracking Individual Clinical Review drug approvals by diagnosis type and the related numbers of requests.

#### Status

The Ministry advised us that the existing Individual Clinical Review (ICR) system provided information, mainly volume and cost data, to support decisions on whether or not a drug should be included in the Formulary. However, the Ministry informed us that ICR was to be replaced by a new program that will capture additional information.

#### TRILLIUM DRUG PROGRAM

#### Recommendation 6

To ensure that the Trillium Drug Program is administered in accordance with legislative requirements, the Ministry of Health and Long-Term Care should:

- ensure that households provide appropriate documentation verifying income; and
- develop and implement appropriate policies and procedures to pursue unpaid deductibles owed to the Ministry.

#### Status

The Ministry informed us that it had implemented monthly inspections of randomly selected household files to verify that Trillium applications were processed with the required income documentation. Whenever the Ministry encountered missing or incomplete documentation, it sent a letter asking the applicant to submit the required information. Similarly, the Ministry was issuing termination letters to households that had not accessed program

benefits in over 18 months, as required by ministry policy.

To reduce the amount of unpaid deductibles in the future, the Ministry implemented policies limiting the quantities of drugs to be dispensed in the third and fourth quarters of a benefit year prior to all deductibles being paid. The Ministry also informed us that it had conducted an analysis in July 2008 to better understand the potential costs of recovering unpaid deductibles. It concluded on the basis of this analysis that collecting unpaid deductibles would not be cost-effective.

#### **SPECIAL DRUGS PROGRAM**

#### Recommendation 7

To ensure that the cost of special drugs used is minimized, the Ministry of Health and Long-Term Care should:

- develop and implement appropriate and consistent policies and procedures relating to the Special Drugs Program that address the supporting claim information required, including details about drug quantities and unit prices paid, and the acceptable reimbursement method;
- consider securing more contracts with drug companies for better special-drug prices; and
- consider conducting periodic reviews of hospital supporting records to verify the accuracy and validity of the amounts claimed.

#### **Status**

The Ministry advised us that it had reviewed the operational procedures for reimbursement of drug costs under the Special Drugs Program. At the time of our follow-up, the Ministry was asking hospitals submitting claims for amounts greater than the prices allowed by the Formulary to submit documentation with the claim. In the Special Drugs Program specifically, where the Ministry has standing agreements with two drug manufacturers that they will not charge the hospitals higher costs than the agreed-upon prices, the Ministry advised us that detailed information on drug quantities and

unit prices paid was not always available from certain hospitals because they dispensed bulk supplies for patients (for instance, through clinics). The Ministry also informed us that it had started transitioning the method used to reimburse hospitals' claims. The new method would reimburse hospitals on the basis of actual drug use rather than on the amount of special drugs purchased. However, some hospitals were not able to apply the new method because administrative records of patients' medication were not always computerized. This was the case, for example, in hospital clinics where patient dispensing (medical administration) records were not kept in electronic format, and actual usage information was not readily available.

With respect to securing more contracts with drug companies for special drugs at better prices, the Ministry informed us that it had reviewed program expenditures and secured contracts for high-cost drug products and their generic equivalents. The Ministry will monitor low-volume and low-cost products for potential agreements should costs increase.

The Ministry informed us that it had conducted reviews on all invoices submitted for reimbursement to identify any excessive unit prices and manufacturer's discounts to be deducted from its payments to hospitals. The Ministry was also reviewing reports on dispensing and usage to confirm the amounts claimed.

#### INSPECTION AND VERIFICATION

#### Recommendation 8

To promote thorough and effective inspections that encourage ongoing compliance, the Ministry of Health and Long-Term Care should:

 conduct a review of the inspection staffing resources and develop an overall audit plan to ensure that sufficient inspection resources are in place to provide adequate inspection coverage across the province;

- on a regular and systematic basis, select dispensing agencies for inspection using appropriate risk factors;
- provide inspectors with ongoing formal audit training in how to conduct an audit, including risk assessment, development of inspection programs, file completion and documentation, and follow-up requirements; and
- deter repeat offenders by enforcing existing legislative penalties.

#### **Status**

At the time of our 2007 audit, the Ministry had three full-time inspection field staff. At the time of our follow-up, the Ministry had hired another three full-time inspectors who had trained as pharmacists, and planned to hire two pharmacy technicians to support routine desk audits. In addition, the Ministry had negotiated an agreement with the Ministry of Revenue to assist with auditing the Ontario Drug Benefit Program in the 2009/10 fiscal year.

The Ministry also advised us that it had developed a training manual that helps it to identify risk and carry out its inspections of agencies. In addition, the Ministry told us it had developed a standardized auditing process to assist new staff and promote consistency and accountability in its inspection procedures.

In our 2007 Annual Report, we noted that ministry policy allowed for interest penalties to be charged when recovery of overpayments is repaid by instalments, and the Ministry could take court action to penalize dispensing agencies for offences identified under the Ontario Drug Benefit Act.

However, the Ministry did neither at that time. The Ministry informed us that provincial offence charges under the Ontario Drug Benefit Act were laid for the first time in April 2009.

#### **CONTRACT MANAGEMENT**

#### **Recommendation 9**

To ensure that the third-party processor of the Trillium Drug Program and the Seniors Reduced Co-payment Program complies with the terms of its contract, the Ministry of Health and Long-Term Care should:

- regularly conduct ongoing audits of the thirdparty processor's records and supporting documents to confirm the accuracy and validity of the amounts invoiced; and
- develop and implement the necessary ministry information reports to facilitate reconciliation of the amounts invoiced.

#### Status

The Ministry informed us that a dedicated staff member was supposed to perform ongoing inspection (a "walk-around") and verification of the third-party processor's records on a monthly basis; however, due to increased workload, the staff member did not perform these inspections regularly in most of 2009, but resumed this responsibility in August 2009. In addition, the Ministry had planned to conduct more complete site visits to the third-party processor on an annual basis, and had done so in October 2007 and May 2009. These site visits included an evaluation of the following areas:

- security clearances for staff;
- safeguarding of personal information;
- inventory of assets;
- training provided to staff;
- quality control of applications, re-assessments, renewals, and receipts; and
- customer calls.

The Ministry of Finance, as part of its Financial Assurance Program, also visited the site of the third-party processor and reviewed its transaction-processing systems and controls in March 2009.

The Ministry told us that it had not yet finished developing the necessary internal information reports to reconcile the amounts invoiced by the third-party processor. The Ministry expected to have some reports for the Trillium Drug Program by the 2009/10 fiscal year and a new client-server application for the Trillium Drug Program and the Seniors' Co-payment Program by April 2011.

#### PERFORMANCE MANAGEMENT

#### **Recommendation 10**

To better monitor and assess the performance of the Ministry of Health and Long-Term Care in meeting its objectives, the Ministry should:

- regularly measure and report actual results against the performance standards, with variances, if any, being resolved on a timely basis;
- comply with its correspondence standards in handling complaints and take corrective action when response times exceed ministry standards; and
- track and analyze the types of complaints and inquiries received about pharmacy practices in order to identify areas for corrective action or improvement.

#### **Status**

In our 2007 Annual Report, we noted that the Ministry had no performance standards for work conducted internally to monitor quality of services and post-payment verification (for example, inspection workload standards). The Ministry indicated to us that it had since established indicators for evaluating performance for these activities, including a target number of audits and inspections to be performed by each inspector. The Ministry was

continuing to monitor inspection workloads and expected that it would be conducting reviews on a bi-annual basis.

In our 2007 Annual Report, we noted that the Ministry was exceeding its standard for responding to complaints and inquiries by an average of 11 days. The Ministry told us that it had since met the standard it had set for correspondence turnaround time—rush requests were processed within 72 hours, biologic requests within 15 business days, and non-rush requests within eight weeks—and that management was monitoring the progress of all requests and reducing backlog by reallocating staffing resources where necessary. The Ministry also developed and implemented a joint tracking system to keep track of drugs-related correspondence and issues and ensure timely turnaround in two program areas.

With respect to complaints and inquiries received about pharmacy practices, the Ministry informed us that it was treating such complaints and inquiries in the same way it had other correspondence: dedicated ministry staff track, file, account for, and respond to such complaints and inquiries. The Ministry also stated that it was referring complaints and inquiries on pharmacy practices to the Ontario College of Pharmacists.