
MINISTRY OF HEALTH AND LONG-TERM CARE

4.09—Drug Programs Activity

(Follow-up to VFM Section 3.09, 2001 Annual Report)

BACKGROUND

The Drug Programs Branch of the Ministry of Health and Long-Term Care is responsible for co-ordinating the provision of prescription drugs and related products to eligible Ontarians. To this end, the Ministry administers transfer payments provided by the Ontario Drug Programs Activity for the Ontario Drug Benefit Program, the Trillium Drug Program, and the Special Drugs Program. Legislative authority for the Ontario drug programs transfer payments are established under the *Ontario Drug Benefit Act*, the *Drug Interchangeability and Dispensing Fee Act*, and the *Health Insurance Act*.

For the 2002/03 fiscal year, the programs' expenditures were \$2.6 billion, of which \$505 million was recovered from the Ministry of Community, Family and Children's Services for drug benefits paid for social-assistance recipients. For the 2000/01 fiscal year, the programs had total expenditures of \$1.98 billion, of which \$413 million was recovered from the then Ministry of Community and Social Services for drug benefits paid for social-assistance recipients.

At the time of our 2001 audit, although we noted that the Ministry had introduced a number of initiatives to manage drug expenditures, we found that the Ministry had not given sufficient consideration to the prices it was paying for drugs. Specifically, we found that:

- Delays in adding approved generic drugs to the Ontario Drug Benefit Formulary and in implementing manufacturers' price reductions resulted in lost savings totalling \$17 million over a two-year period.
- The Ministry had not reviewed the effectiveness of the generic pricing practices or routinely compared the prices it was paying for drugs with the prices paid by other jurisdictions. In this regard:
 - For a sample of generic products we tested, the Ministry would have saved approximately \$54 million annually had it paid the same prices as Saskatchewan for these products.
 - Another jurisdiction, using a competitive acquisition process, was able to obtain prices for certain drugs that were, on average, 60% lower than those obtained by Ontario. Annual potential savings to the Ministry could have been as much as \$140 million if it had been able to obtain the same prices for these drugs.

The Ministry generally had adequate procedures in place to ensure compliance with legislation and that claims were properly approved, processed, and paid. However, we noted that:

- The Ministry had not substantiated whether as many as 180,000 of the recipients who were granted temporary eligibility for the Ontario Drug Benefit Program in 1999/2000 were in fact entitled to benefits.
- The Ministry forgave \$1.5 million to be recovered from pharmacies resulting from a 1997 verification of claims for limited-use drugs.
- The Ministry needed to 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).

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

CURRENT STATUS OF RECOMMENDATIONS

According to information obtained from the Ministry of Health and Long-Term Care, the Ministry has taken some action on most of the recommendations we made in our *2001 Annual Report*. The current status of our recommendations is as follows.

ONTARIO DRUG BENEFIT AND TRILLIUM DRUG PROGRAMS

Drug Use Review

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.*

Current Status

The Ministry advised us that:

- The Ministry “has established the Drug Strategy Review (DSR) with a mandate to find ways to optimize pharmaceutical care in order to ensure access to the drugs Ontarians need, now and in the future. The DSR is undertaking a review of the Ontario Drug

Benefit Program and developing a strategy aimed at improving pharmaceutical care for patients that will include an examination of access to new and existing drugs, cost-effectiveness and pricing of drugs, appropriate drug use, and program administration.”

- A ministry-funded committee, the Ontario Program for Optimal Therapeutics, was focusing on assessing the utilization of drug-use prescribing guidelines. Two areas for review (statins and opioid narcotics) had been identified. The Ministry was reviewing the process for conducting the review of these two areas with the pharmaceutical industry and the Drug Utilization Advisory Committee to ensure that it was aligned with other ongoing work, such as the Drug Benefit Formulary modernization undertaken by the Drug Quality and Therapeutics Committee (DQTC).
- The Ministry was using work conducted by the Institute for Clinical Evaluative Sciences in a number of therapeutic areas to support ongoing work with DQTC’s Formulary modernization and to identify areas that may benefit from additional measures to improve prescribing and utilization.

The Ministry informed us that it had contacted the College of Physicians and Surgeons of Ontario and was in ongoing discussion with the College to generate a list of physician identification numbers for the Health Network System database to ensure that prescribers can be identified. In addition, pharmacies have been instructed that valid identification numbers must be used unless the situation is exceptional.

The Drug Formulary—Timely Updates to 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.*

Current Status

The Ministry indicated that ministry staff had met with Health Canada staff to further harmonize the Ministry’s drug-listing process for generic products with that of Health Canada. The Ministry also participated in a federal/provincial/territorial discussion on streamlining generic products in March 2003 and is currently working on streamlining proposals to ensure timely updating of the Formulary.

According to the Ministry, the Ministry will be considering options for decreasing the time for listing streamlined generic products, which would also enable the Ministry to take timelier advantage of manufacturers’ price reductions.

The Drug Formulary—Formulary Modernization

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.

Current Status

The Ministry advised us that, in August 2002, the Drug Quality and Therapeutics Committee discussed the review of a number of therapeutic categories of drugs and that six drug category reviews—for example, reviews of drugs for osteoporosis and multiple sclerosis—had been completed since December 2002. Three additional reviews had been initiated and were to be completed early in the 2003/04 fiscal year.

Pricing

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.

Current Status

According to the Ministry, Ontario is a member of the Federal/Provincial/Territorial Working Group on Drug Prices, which is examining price initiatives across jurisdictions. As part of its examination of pricing of drugs, the Drug Strategy Review is to examine medium- and long-term pricing options for both brand-name and generic drugs to achieve fair and reasonable prices for new and existing drugs.

The Ministry advised us that it was reviewing the present pricing policy for generic drugs.

Pricing—Pricing Options

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.

Current Status

As mentioned earlier, the Ministry is working with other Canadian jurisdictions on this issue. As part of this work, the Ministry is to be undertaking research on key pharmaceutical policy trends, which would include a review of pricing strategies in select jurisdictions.

Written Agreements with Brand-name Drug Manufacturers

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.*

Current Status

According to the Ministry, an internal report on the written agreement process had been completed at the time of our follow-up, and a formal review of the written agreement process is to be undertaken by the Drug Programs Branch. The Ministry indicated that a business case for the formal review had yet to be prepared to secure resources and to hire an external consultant.

Health Network System

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.*

Current Status

At the time of our 2001 audit, a vendor had been selected without using a competitive process to provide long-term services in developing and maintaining the Health Network System. The Ministry advised us that a consultant had recently prepared a business case and a request for resources (RFR) for a vendor of record to conduct a value-for-money audit of the current contractual arrangements with this long-term-service provider. The business case and RFR were in the process of receiving approval from ministry senior management.

Health Network System—Claims Processing

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.*

Current Status

The Ministry advised us at the time of our follow-up that no changes had been made to the verification process and that the Ministry would continue to review the verification process to identify opportunities to address the first part of our recommendation.

The Ministry also advised us that it was continuing to conduct periodic reviews of exception reporting and was working with the Ministry of Community, Family and Children's Services (the former Ministry of Community and Social Services) to ensure recipient information is as accurate and up to date as possible.

TEMPORARY ELIGIBILITY

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.*

Current Status

The Ministry advised us that the Ministry of Community, Family and Children's Services (the former Ministry of Community and Social Services) had moved from a weekly to a daily feed to update eligibility and personal information contained on the Health Network System. The Ministry indicated that the daily updates would be monitored to determine whether continuing them is operationally sustainable. The Ministry also indicated that it would review the number of temporary eligibility claims in the 2002/03 fiscal year and

compare it to the numbers in previous years. Further steps would depend on the results of this review.

WARNING AND INFORMATION MESSAGES

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.*

Current Status

According to the Ministry, staff from the Drug Programs Branch will be conducting a preliminary investigation of additional warning and information message modules that are available and will consider including these modules in the next request for proposals with the data supplier. The Branch also intends to investigate the feasibility and benefits of adding a therapeutic duplication check to the Network.

Health Network System—System 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.*

Current Status

According to the Ministry, at the time of our follow-up:

- The security administration process had been reviewed and is now managed through one branch manager. Notification of staff changes had been included in the security review.
- The Drug Programs Branch was working with the Health Network System service provider to consolidate all security-related documentation and to update the

documentation where appropriate. A new security document had been finalized and approved.

- The replacement date for the current communications network had been re-scheduled from April 2003 to April 2004. The Ministry indicated that it would continue to implement security procedures as required.

Contract Management

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.

Current Status

According to the Ministry, staff from the Ministry's internal audit branch have developed procedures for periodic reviews to address this recommendation. Drug Programs Branch staff met with internal audit staff in February 2003 to review the procedures.

Inspections and Verification—Inspection Resources

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.*

Current Status

At the time of our follow-up, the Ministry advised us that:

- Due to the public service strike in 2002 and the implementation of projects that had a higher priority than the Pharmaceutical Audit System, implementation of Phase II of the system had been deferred until January 2003. Phase II has now been implemented, and a training program for appropriate staff has now been developed.
- Inspection plans were in place.
- The policies and procedures in the draft manual, which incorporate management review of the work of inspectors, have been reviewed, finalized, and put in place.

Inspections and Verification—Inspection Coverage

Recommendation

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

Current Status

The Ministry advised us that the review of resources in place to inspect pharmacies had yet to be undertaken. The Drug Programs Branch was working with the Ministry's Fraud Programs Branch to establish the terms of reference and timeline for the review.

Inspections and Verification—Verification Letters

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.

Current Status

The Ministry advised us at the time of our follow-up that a review of audit activities in other provinces was being planned. When the review is complete, the Ministry intends to determine which additional procedures are to be implemented in Ontario.

Inspections and Verification—Verification of Limited-Use Drug Forms

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.*

Current Status

The Ministry indicated that it was still planning to carry out audits of limited-use claims in the future and would make recoveries where claims were not supported by valid documentation. As required, the Ministry obtained Order-in-Council approval to forego the recovery of the outstanding funds from pharmacists related to the limited-use audit carried out in 1997, pursuant to subsection 5(1) of the *Financial Administration Act*.

TRILLIUM DRUG PROGRAM

Recipient Deductibles

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.*

Current Status

According to the Ministry, in order to address the possibility of recipients receiving program benefits in one quarter while underpaying their deductibles in other quarters, the Health Network System (HNS) no longer allows pharmacists to dispense more than 30 days of supply of a drug beyond the end of the third quarter of the benefit year (May 30). The HNS now also does not allow a pharmacist to override this control if a client's claim occurs during the third quarter of the year and may result in an underpayment of the deductible. The Ministry is examining options for the recovery of underpaid deductibles.

The Ministry also indicated that the Drug Programs Branch had met with the Canada Customs and Revenue Agency (CCRA) to explore an electronic feed of income data from CCRA. If an electronic feed can eventually be put in place, the Branch will be able to check the seniors' data and validate Trillium data on a regular basis.

SPECIAL DRUGS PROGRAM

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.

Current Status

The Ministry advised us that, in December 2002, a discussion paper with short- and long-term recommendations was approved by the Minister's office. In the short term:

- New brands/formats of existing substances that treat one of the conditions covered by the Special Drugs Program (SDP) are to be added to the list of drugs covered by the SDP to provide choice of products to physicians.
- The SDP is to be automated to actively manage and increase accountability in the system.

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- The Ministry has informed hospitals, stakeholder groups, and manufacturers of the changes to the SDP and the process for adding new brands/formats of existing substances.

The Ministry also indicated that it would continue to consult with stakeholders as it moves towards the longer-term objective of integration of the Special Drugs Program with the Trillium Drug Program. The Ministry noted that the benefits of integrating the two programs include equal and convenient access to drug therapy for all patients, fair treatment of all manufacturers, and increased accountability for claimants (that is, patients, physicians, and institutions/pharmacies). However, a target date for the integration of the two programs had not been set.

Payment Processing

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.*

Current Status

According to the Ministry, at the time of our follow-up:

- Procedures had been updated to ensure routine checking of all invoices from hospitals.
- Automation of the Special Drugs Program (SDP) would be piloted at three hospitals in April 2003. Initially, the automation would involve online claims adjudication for two of the eight categories of products that are reimbursed under the SDP. Automation would then be rolled out to other SDP hospitals linked to the Ministry's Health Network System over a period of three to four months.
- Hospitals not linked to the Network would need to purchase software and hardware in order to get the linkage. Automation of claims from these hospitals would occur over a longer period, likely four to six months.

The Ministry also indicated that, during the phasing-in of automation, both the manual invoicing and online adjudication systems for reimbursements would be in place. In addition, options for automating the other six categories of SDP drugs were being researched by category, since each category has unique issues with respect to, for example, distribution and monitoring programs needed to ensure the safety of therapy.

The Ministry also indicated that it now has a process in place to check that each invoice has been properly priced and that all proper documentation, including support for administrative costs paid to hospitals, has been submitted.

PERFORMANCE MEASUREMENT AND REPORTING

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.

Current Status

The Drug Programs Branch has posted its annual report on the ministry Web site (at http://www.health.gov.on.ca:80/english/public/pub/ministry_reports/odb_report01/drug_rep.html). The report includes sections on: financial indicators; clinical indicators; customer service; and operational policy.

The Ministry advised us that, in response to the *2003 First Ministers' Accord on Health Care Renewal*, the Drug Programs Branch identified 11 possible performance measures. Three of these measures are to be investigated further through the Pharmaceutical Care Working Group, which was one of the five working groups established in response to The Commission on the Future of Health Care in Canada (headed by Roy Romanow) and the First Ministers' Health Accord.