Ministry of Health and Long-Term Care

Ontario Public Drug Programs

1.0 Summary

About four million Ontarians receive drug coverage through the Ontario Public Drug Programs (Programs) each year. The Ministry of Health and Long-Term Care (Ministry) is responsible for administering the Programs, which cover most of the cost of over 4,400 drug products listed on the Ontario Drug Benefit Formulary (Formulary), over 1,000 drugs through the Exceptional Access Program list (non-Formulary), certain disease-specific programs as well as various professional pharmacy services received by eligible Ontarians.

The Programs include the Ontario Drug Benefit Program, the New Drug Funding Program and other programs relating to specific drugs and diseases. The Programs' mission is to improve patients' access to drugs, promote the appropriate use of drugs, ensure the sustainability of the health system through evidence-based decision-making, and strengthen Ontario's position as a public payer for drugs.

Eligibility for the Programs depends on criteria such as age, residence in a care setting, receipt of home care services through the Ministry's Home and Community Care Program, income level and others. Most of the eligible recipients are required to pay some portion of the cost of their prescription drugs in the form of co-payments, with or without deductibles.

Through the Exceptional Access Program, the Ministry also covers people eligible to receive Ontario Drug Benefit Program benefits who have been prescribed certain drugs for conditions of use that are not on the Formulary, through a case-by-case review process of determining if the request meets approved clinical criteria.

More than 4,260 pharmacies and other entities dispense drugs in Ontario; 97% of these are retail pharmacies. Seniors aged 65 and over living in their own home, and social assistance recipients (eligible recipients of Ontario Works and the Ontario Disability Support Program) received over 70% of the drug benefits. The other 30% went to residents of long-term-care homes and Homes for Special Care, recipients of home care services, and people enrolled in other programs.

In the 2016/17 fiscal year, the Programs' total expenditure was $5.9 billion (before rebates of $1.1 billion paid to the Ministry by drug manufacturers); the expenditure of the Ontario Drug Benefit Program alone amounted to $5.4 billion when co-payments and deductibles were included. **Figure 1** shows the breakdown of the Ontario Druge Benefit Program's expenditures by expenditure type.

In addition, the Ministry paid $83 million for professional pharmacy services, such as medication reviews and administration of the influenza vaccine.

Figure 1: Breakdown of Ontario Drug Benefit Program Expenditures, 2016/17

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

Expenditure Type	Amount ($ million)
Drug costs	4,555
Markups	320
Dispensing fees*	1,204
Co-payments/deductibles	(689)
Total	**5,390**

* Includes $10 million compounding fees.

One of the Ministry's key responsibilities is to negotiate with drug manufacturers to achieve the best price possible for drugs covered by the Ontario Public Drug Programs. According to the most recent data available, the cost associated with brand-name drugs in 2015/16 was about two-thirds of total drug costs, and the cost associated with generic drugs that year accounted for the remaining one-third, under the Ontario Drug Benefit Program. (These drug costs are before rebates, co-payments and deductibles, but include mark-ups and dispensing fees paid to pharmacists.)

Prices of Brand-Name Drugs

For brand-name drugs, we noted that, over the last 10 years, the Ministry has taken initiatives, some of them with other Canadian provinces, to negotiate contracts with drug manufacturers that often resulted in receiving rebates, such as volume discounts, from the manufacturers. However, we noted the following:

- **Negotiations for brand-name drugs have led to significant rebates from drug manufacturers, but it is difficult to know whether the Ministry is obtaining the best possible value compared to other jurisdictions.** The Ministry received $1.1 billion in rebates from drug manufacturers in 2016/17. However, the Ministry could not determine how the confidential discounted prices of the brand-name drugs compared to prices paid by other countries, because the actual cost to payers outside of Canada is not disclosed by governments.
- **The processing of rebates for brand-name drugs is too slow and prone to error.** The Ministry took over six months on average to invoice drug manufacturers after the date when rebates could be recovered. Based on our sample of manufacturers' invoices for a 12-month period, and using the Province's average liquid reserve investment return for 2016/17, six months of lost interest income would equate to about $2.2 million. Further, the Ministry has made some errors, totalling over $16 million, in one case resulting in failure to invoice over $10 million. Although the Ministry eventually recovered the amount when the drug manufacturer informed it of its error, there is a risk that future errors may be left undiscovered.

Prices of Generic Drugs

While generic drugs accounted for about one-third of the total drug costs in 2015/16, they represent roughly two-thirds of the total volume of drug prescriptions claimed under the Ontario Drug Benefit Program. For certain generic drugs, we noted that the Ministry paid significantly higher prices than other countries as well as some Ontario hospitals. In particular:

- **Generic drug prices in Ontario have dropped significantly in the last 10 years, but the Province still pays more than foreign countries.**
  - Since 2006/07, the Ministry has negotiated lower prices for generic drugs through a number of reforms, including participation in the pan-Canadian Pharmaceutical Alliance (Alliance), which negotiates collectively on behalf of all provinces, territories and federal drug plans. The Alliance established two major initiatives: one reduced the Canadian prices of 18 highly used

generic drugs, and another introduced a tiered pricing framework for generic drugs entering the Canadian market on or after April 1, 2013. The Patented Medicine Prices Review Board (an independent quasi-judicial body with authority to regulate the prices of patented medicines sold in Canada) performed an analysis of the generic drugs included in these initiatives and found that the median prices of generic drugs from seven other countries were 28% below Canadian prices as of March 2015. Due to timing, the Board's analysis did not take into consideration the six highly used generic drugs that are priced at 15% of the reference brand price, effective April 2017.

- We compared a sample of 20 common generic drugs highly used under the Ontario Public Drug Programs with New Zealand prices (not part of the seven countries mentioned above). Our analysis shows that, in 2015/16, Ontario paid roughly $100 million (or about 70%) more for the same drugs of the same strengths than New Zealand. Unlike New Zealand, the Ministry did not tender competitive bids from drug manufacturers. However, we recognize that one consequence of New Zealand's purchasing approach is that there is a potential that when a supplier wins a tender and becomes the sole supplier of a drug, drug supply shortages may occur.

- **The Ministry paid significantly higher amounts for a number of commonly used generic drugs than some Ontario hospitals.** Hospitals purchase their drugs without going through the Ministry's Programs and pay for them out of their global budget (which is also funded by the Ministry). We compared a sample of common generic drugs that were used in both the community setting and the hospital setting, and found that hospitals were obtaining lower prices than the Ministry by $271 million (or 85%) in 2016/17. Although there is no guarantee that the Ministry could obtain the same prices for these same drugs, it indicates that opportunities exist for further price reductions on generic drugs. While the Ministry's payments to pharmacies for generic drugs are based on a pre-set percentage of the price of the equivalent patented drugs (called the Tiered Pricing Framework), Ontario hospitals typically use group purchasing organizations to tender competitive bids.

Exceptional Access Program

Another key responsibility of the Ministry is to ensure that eligible recipients have timely access to drugs when they need them. We found that the Ministry was able to fulfill this mandate for the majority of recipients, paying for their drug costs in a timely manner when their prescribed drugs are listed on the Formulary. We found as well that the process of listing brand-name drugs on the Formulary was based on clinical evidence and cost-effective analysis reviewed and recommended nationally by the Canadian Agency for Drugs and Technologies in Health, and the Ministry's own Committee to Evaluate Drugs, as well as through its negotiation processes and agreements with drug manufacturers.

However, delays are common with people who require exceptional approval for the cost of their prescribed drugs to be reimbursed on a case-by-case basis. In 2016/17, Ministry costs associated with drugs approved through the Exceptional Access Program were about $810 million for about 65,850 Ontarians who had utilized approximately 580 drugs from the list of over 1,000 drugs requiring case-by-case review to meet approved criteria. Our audit noted the following:

- **Many patients requesting exceptional drug coverage waited excessively.** The Ministry does not routinely track or publicly report the overall patient experience time for each application (defined as the time between when the Ministry receives the original request for

coverage and when it replies with its decision). Our audit found that overall patient experience times for many requests were too long. For example, in 2016/17, the overall time taken for the two most requested biologic drugs (over 7,800 total requests) was, on average, approximately seven to eight weeks.

- **The Ministry has acknowledged weaknesses in processing exceptional access requests since 2010.** The Ministry has long acknowledged the shortcomings in the largely manual system that processes requests, and proposed information-system solutions to address the delays in 2010. However, the initial proposals were not approved to proceed. In 2015, the Ministry proposed another new system to automate the processing of requests. Assuming the new system is complete in October 2018, as planned, it will have been eight years after the Ministry acknowledged the weaknesses in 2010. The Ministry estimated that the total project investment for the new system will have been approximately $14.4 million between 2016/17 and 2018/19.

Oversight of Payments to Pharmacies

In 2016/17, out of the more than 4,260 pharmacies, the Ministry inspected 286 pharmacies and recovered $9.1 million in inappropriate claims. However, our audit identified many other inappropriate claims and payments not inspected and/or recovered by the Ministry, and also noted that the Ministry delayed in acting on potential cases of fraud. Specifically:

- **The Ministry did not inspect and/or recover many payments for invalid claims, leading to about $3.9 million of inappropriate payments.**
  - In 2015/16, the Ministry paid approximately $952,000 for claims made in the name of deceased patients, but recovered only about $42,400 from pharmacies as a result of its inspections, resulting in about $910,000 not recovered.
  - In 2015/16, the Ministry paid about $3 million for claims that could not be reversed online by pharmacists, but recovered only about $900,000 from pharmacies through inspections, resulting in about $2.1 million not recovered.
  - During the 2016 calendar year, the Ministry paid about $922,000 for drugs received by patients whose age and gender did not meet the Ministry's criteria for the limited-use drugs, although in some cases the use of these drugs could be clinically appropriate. The Ministry did not know why the pharmacists were not verifying patients' age and gender before they claimed these drugs for their patients.
- **The Ministry did not refer several potentially fraudulent billings to the Ontario Provincial Police (OPP) in a timely manner.** The Ministry did not refer any cases to the OPP in both 2013/14 and 2014/15, but forwarded two and 13 cases for investigation in 2015/16 and 2016/17, respectively. Representatives from the OPP told us that eight of the 13 files were too old to investigate further. The Ministry referred these eight cases to the OPP between 3.5 and five years after their initial inspections, even though the Ministry suspected fraudulent billing in these cases. For example:
  - In all eight cases, the Ministry uncovered discrepancies between drug purchases and sales where the pharmacists could not explain why there were not sufficient drug inventory purchases to cover the sales at their pharmacies.
  - In three of the eight cases, either the physicians or patients denied that prescriptions were actually prescribed or received, after the Ministry sent letters and asked them to verify the existence of the claims.

MedsCheck Program

The Ministry does not know if the MedsCheck program ($550 million between 2008/09 and 2016/17) is effective. MedsChecks are consultations provided by a pharmacist to a patient who is taking three or more chronic medications (or meets certain other criteria), to review the patient's medication profile and identify and resolve drug-related problems. In 2007, when MedsCheck was established, the Ministry set as its objectives to promote healthier patient outcomes, quality of life and disease self-management, and to improve patient knowledge and understanding of, and adherence to, drug therapy. Yet the Ministry has not been able to demonstrate the value of the MedsCheck program and does not know if the MedsCheck program is effective in meeting the intended objectives, primarily due to lack of clinical data collected on patient outcomes.

Opioid Crisis

The Ministry spent $157 million through the Ontario Drug Benefit Program on opioids for about 720,000 recipients in 2016/17.

Despite numerous initiatives taken by the Ministry in dealing with the recent opioid crisis in the province, it does not have the critical information needed to inform its decisions in addressing the issues. Specifically, the Ministry does not know whether individuals overdosed or died from using prescription opioids or illicit opioids.

This report contains 10 recommendations, consisting of 20 actions, to address our audit findings.

Overall Conclusion

Our audit concluded that the Ministry of Health and Long-Term Care (Ministry) had effective systems and procedures in place to ensure that eligible recipients have timely access to Formulary drugs and that the process of listing drugs on the Formulary was based on clinical evidence and cost-effective analysis.

However, the Ministry was unable to ensure that brand-name drugs were funded at the best possible prices compared to other countries, because the actual drug costs to payers outside of Canada are not disclosed by governments. As well, the Ministry has not recently evaluated the suitability of other pricing models for determining generic drug pricing, such as tendering, as noted in other countries and Ontario hospitals that obtained lower prices, to reduce prices for generic drugs.

Further, we found that the Ministry's systems and procedures relating to reimbursing the cost of non-Formulary listed drugs under the Exceptional Access Program were not always timely. The Ministry handles these requests on a case-by-case basis using a manual system.

We also concluded that the Ministry's oversight of payments to pharmacies was not always in accordance with legislation and agreements, as evidenced by many invalid claims and payments to pharmacists that were not inspected and/or recovered from these pharmacies.

While the Ministry publicly reports on some program statistics and performance, it could be doing more to collect and analyze complete and accurate data for decision-making and program improvements, such as evaluating the MedsChecks program and assessing the effectiveness of its initiatives in addressing the recent opioid crisis in Ontario.

OVERALL MINISTRY RESPONSE

The Ministry appreciates the work of the Auditor General and welcomes the advice on how to improve the Ontario Public Drug Programs. We acknowledge the recommendations and are committed to ensuring they are reflected in our actions to strengthen accountability, oversight, value for money and operational excellence, including continuing to leverage information technology in our program delivery. The recommendations within this report, in a number of

instances, build upon work that had already been undertaken, including: expanding our capacity for negotiations and contract management; modernizing the Exceptional Access Program to ensure timeliness of access for drug funding; enhancing our audit and investigation ability to address inappropriate or potentially fraudulent claims; evaluating the impact of pharmacy services, such as the MedsCheck program; and our continuous efforts to improve the affordability of medicines for the province.

The area of pharmaceuticals is complex and ensuring appropriate access to necessary prescription medicines requires difficult, compassionate and evidence-based decisions, taking into account both clinical and cost-effectiveness considerations. Ontario has been at the forefront of the Canadian efforts to improve consistency of access, affordability, and decreased duplication of effort through the Canadian Agency for Drugs and Technologies in Health (CADTH) and the pan-Canadian Pharmaceutical Alliance (pCPA). These efforts have resulted in significant savings to Ontario and Canada as a whole.

The Ministry recognizes there are further opportunities to obtain value for the Ontario Public Drug Programs through continued aggressive negotiations with brand-name drug manufacturers, building on existing success, and learning from international experiences and how they might be adapted for the Canadian context. In addition to the observations made in this report by the Auditor General regarding Canadian generic pricing, the report also identifies that Canada has made the most significant gains with reducing its prices over the last seven-year period. Further reductions in prices were implemented in April 2017 that are projected to provide an additional $30 million savings annually to government. At the time of this response, the pCPA is currently in discussion with the generic industry in Canada with the purpose of continuing to bring greater value and further savings to the participating jurisdictions, including Ontario, while ensuring that we have a secure supply of these critical medicines.

Ontario is recognized as a leader in the delivery of public drug programs and will utilize the important learnings from this report to inform its work both in Ontario and within the larger pan-Canadian context.

2.0 Background

The Ministry of Health and Long-Term Care (Ministry) is responsible for administering the Ontario Public Drug Programs (Programs), which provide drug coverage to eligible Ontarians for over 4,400 drug products listed on the Ontario Drug Benefit Formulary (Formulary) and also through other programs. Non-Formulary drugs may be considered for coverage on a case-by-case basis through the Exceptional Access Program. More than 4,260 pharmacies and other entities dispense drugs in Ontario; 97% of these are retail pharmacies. The Programs' mission is to improve patients' access to drugs, promote the appropriate use of drugs, ensure sustainability of the health system through evidence-based decision-making, and strengthen Ontario's position as a public payer for drugs. About four million Ontarians receive prescription drugs through the Programs each year.

The *Ontario Drug Benefit Act* (Act) gives the government the authority to designate an Executive Officer to administer the Programs. The Executive Officer is the Assistant Deputy Minister of the Ministry's Ontario Public Drug Programs Division. Through this Act, the Executive Officer has the power, among other things, to set eligibility criteria for the Programs, keep and maintain the Formulary, and negotiate pricing agreements with drug manufacturers. In the fiscal year ending March 31, 2017, the Ministry had about 128 staff in its Ontario Public Drug Programs Division for a total cost of about $25.8 million to administer the Programs.

2.1 The Ontario Public Drug Programs

The publicly funded drug system in Ontario is complex and involves various players and activities. The following sections explain three key areas:

- eligible recipients of the Ontario Public Drug Programs (**Section 2.1.1**);
- the role of drug manufacturers with regard to the Ontario Public Drug Programs (**Section 2.1.2**); and
- Ministry payments to pharmacies and other dispensers (**Section 2.1.3**).

2.1.1 Eligible Recipients of the Ontario Public Drug Programs

Specific groups of Ontarians are eligible for public drug coverage that the Province provides to subsidize their purchase of prescription drugs. The eligibility criteria for coverage are set out in the *Ontario Drug Benefit Act*, its regulations and Ministry policy. In 2016/17 the Ontario Public Drug Programs had a total expenditure of $5.9 billion (before aggregate rebates from drug manufacturers—governments and manufacturers worldwide do not reveal rebates by individual drug or manufacturer). **Figure 2** breaks down the total expenditure by types of recipients, and shows that seniors aged 65 years and over living in their own home received over half of the drug benefits.

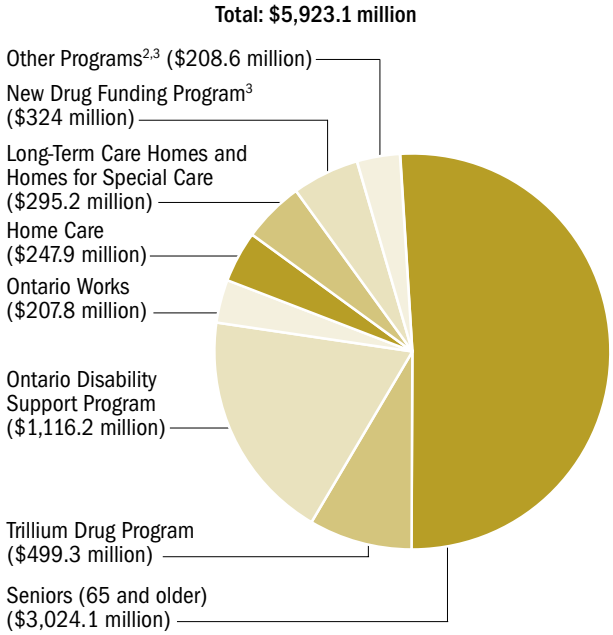
Ontario Public Drug Programs

Eligible Ontarians may receive their drug coverage through any of the following programs:

- The *Ontario Drug Benefit Program* is the largest of the Ontario Public Drug Programs ($5.4 billion, or 92% of total expenditures, in 2016/17). It provides coverage for prescription drugs to Ontario seniors (those 65 and older); social assistance recipients (Ontario Works and Ontario Disability Support Program, overseen by the Ministry of Community and Social Services); persons receiving home care services through the Ministry's Home and Community Care Program; Ontarians with high drug costs relative to their household income (through the Trillium Drug Program, discussed next); and residents of Homes for Special Care and long-term-care homes. Recipients are required to pay a portion of the cost of their drugs in the form of deductibles and/or co-payments. **Figure 3** summarizes the amount of deductibles and co-payments by eligibility category. The total of these deductibles and co-payments was $689 million, as shown in **Figure 1**.
- The *Trillium Drug Program* ($499 million in 2016/17) is included in the *Ontario Drug Benefit Program*. It provides assistance to people who are under 65 years old and have prescription drug costs that are high relative to their income.

Figure 2: Ontario Public Drug Programs Expenditures[1] by Types of Recipients, 2016/17

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



1. Amount before rebate received by the Ministry.
2. Other Programs include the Special Drugs Program, Inherited Metabolic Disease Program, Respiratory Syncytial Program and Visudyne Program.
3. All programs shown except for the New Drug Funding Program and the category Other Programs come under the Ontario Drug Benefit Program, whose total cost is $5.4 billion.

Figure 3: Deductible Amounts and Co-payments, by Category of Recipient Eligibility, Effective August 1, 2016
Source of data: Ministry of Health and Long-Term Care

Eligible Category	Deductible(s) ($)	Co-Payments ($)
Person aged 65 or older		
Single senior, income greater than $19,300	100.00	6.11[1]/2.83[2]
Senior couple, income greater than $32,300	100.00 each	6.11[1]/2.83[2]
Single senior, income less than $19,300[3]	–	2.00
Senior couple, income less than $32,300[3]	–	2.00
Other		
Resident of long-term-care home	–	2.00
Resident of a Home for Special Care	–	2.00
Recipient of professional home care services	–	2.00
Recipient of benefits from Ontario Works or Ontario Disability Support Program	–	2.00
Recipient of Trillium Drug Program	Income-based	2.00

1. Retail pharmacy.
2. Hospital pharmacy (the drug product is supplied in a pharmacy operated in a hospital under the *Public Hospitals Act*).
3. Seniors with low income may apply for the Seniors' Copayment Program to have the deductible removed and pay up to $2.00 co-payment per prescription.

- The *New Drug Funding Program* ($324 million in 2016/17) covers the costs, through Cancer Care Ontario, of certain injectable (intravenous) cancer drug therapies administered in specific out-patient settings, such as community hospitals and regional cancer centres. Refer to **Section 3.02**, "Cancer Treatment Services," in this Annual Report for further details.
- The *Special Drugs Program*, the *Inherited Metabolic Diseases Program*, the *Respiratory Syncytial Virus Program* (for a respiratory infection in infants) and the *Visudyne Program* (for age-related macular degeneration, an eye condition) cost a total of $209 million in 2016/17. The Special Drugs Program provides funding to cover the costs of about 300 drugs and nutritional products provided to hospital out-patients for the treatment of specific health conditions. The latter three programs provide assistance to people who have been diagnosed with specific diseases and/or conditions.

Jurisdictions across Canada each have drug programs with differing eligibility requirements. **Appendix 1** describes the main drug programs in selected Canadian provinces.

Requests for Exceptional Access

An eligible patient under the Ontario Drug Benefit Program who requires a drug that is not listed on the Formulary may be able to obtain the drug through the Ministry's Exceptional Access Program. A physician or nurse practitioner requests the drug on the patient's behalf. Ministry staff review the request and determine eligibility on a case-by-case basis using Ministry-specified, evidence-based criteria. (This program is discussed in **Section 4.3**.) The Ministry provides access to these non-Formulary drugs in certain circumstances where Formulary drugs were ineffective or not tolerated, or no alternative was available on the Formulary.

The Ministry may choose to fund drugs on a restricted basis through the Exceptional Access Program, and not as a general benefit through the Formulary, because these drugs are more costly and restricting access to a criteria-based process allows costs to be contained. In some cases, the drugs may have limited evidence to support broad use; therefore, it is important to make sure that the patients

receiving these drugs actually need them. Similar special access programs are found in drug plans in other provinces and countries.

In 2016/17, Ministry costs associated with drugs approved through the Exceptional Access Program were about $810 million for about 65,850 Ontarians who had utilized approximately 580 drugs from the list of over 1,000 drugs requiring case-by-case review to meet approved criteria.

Ontario Public Drug Programs Expenditures and Statistics

The number of drug recipients covered through the Ontario Public Drug Programs increased by almost 30% between 2006/07 and 2016/17, from 3.1 million to 4.0 million. The Programs' drug expenditures grew at a quicker pace. **Figure 4** shows the 11-year trend of the annual total Programs' expenditures from 2006/07, when the Ministry began negotiating rebates on brand-name (that is, patented) drugs, to 2016/17. Total expenditures before rebates increased during these years by 60%, from $3.7 billion to $5.9 billion. This increase is due to many factors, including the increased use of newer and more expensive drugs, the aging population, the growing number of recipients, and the use of drugs that come out of new areas of research into new diseases.

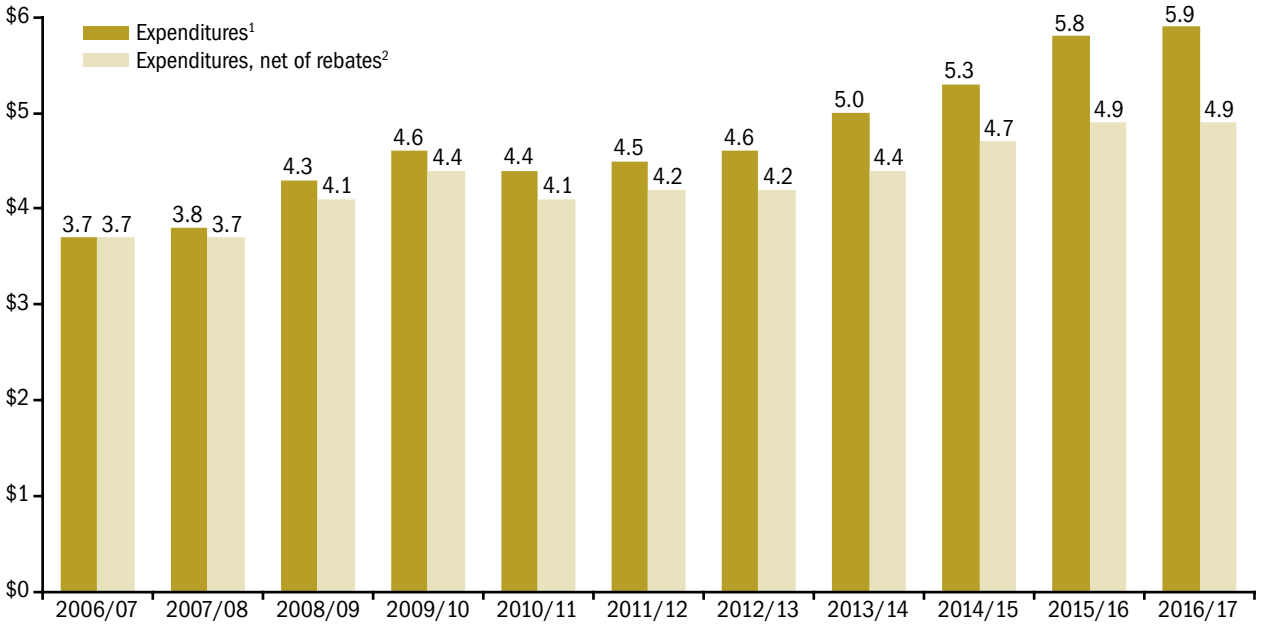
Figure 4 also shows the 11-year trend of expenditures net of the negotiated rebates. The *net of rebates* expenditures increased by 32% from $3.7 billion to $4.9 billion, which was well below the 60% increase in total expenditures *before rebates*.

The Ministry reports annually on its program statistics to help further clarify the picture of the Province's eligible recipients. For example:

- **Appendix 2** lists the top 10 therapeutic drug classes by drug costs in 2015/16.
- **Appendix 3** lists the top 10 therapeutic drug classes by number of users in 2015/16.
- **Appendix 4** lists the top 10 drugs by their cost to the Programs in 2015/16.

Figure 4: Ontario Public Drug Programs Expenditures, 2006/07–2016/17 ($ billion)

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



1. Amounts include expenditures from the Ontario Drug Benefit Program, New Drug Funding Program, Special Drugs Program, Inherited Metabolic Disease Program, Respiratory Syncytial Program and Visudyne Program. These amounts include drug costs, markups, dispensing and compounding fees, and are net of recipients' co-payments and deductibles.
2. Drug manufacturers rebate to the Ministry a portion of the total price based on agreements they negotiate with the Ministry. Rebates began to increase in 2010/11 after the Pan-Canadian Pharmaceutical Alliance was established to leverage the collective purchasing power of the provinces and territories in negotiations with drug manufacturers.

2.1.2 The Role of Drug Manufacturers in the Ontario Public Drug Programs

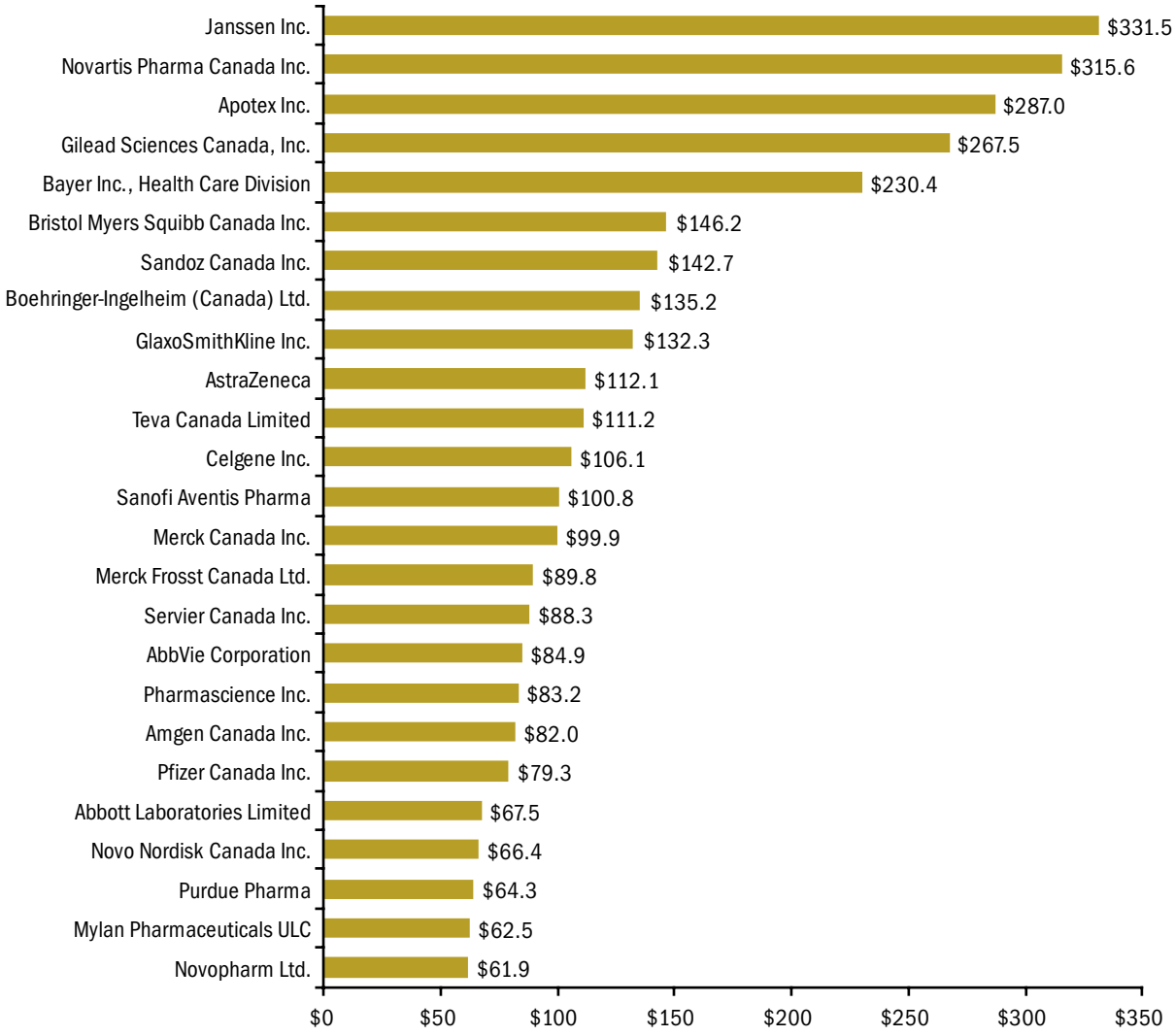
Drug Manufacturers

Drug manufacturers produce and sell drugs to purchasers in Ontario. Manufacturers that develop new medicines typically obtain Canadian patents on those drugs and sell them under a brand name. A patent provides the patent holder with exclusive rights for approximately 20 years from the date of filing. Following the expiry of relevant patents on a drug, competing firms may enter the market to sell copies of the drug with the same active ingredient, known as generic drugs. These generic drugs are approved by Health Canada for sale, and most are also approved by Health Canada as chemically equivalent to the brand-name drug.

Figure 5 shows a breakdown of the top 25 drug manufacturers by drug cost paid by the Ontario Drug Benefit Program for 2016/17.

Figure 5: Top 25 Drug Manufacturers by Drug Cost[1] Paid by Ontario Drug Benefit Program,[2] 2016/17 ($ million)

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



1. Drug costs are based on the publicly available list prices and may not reflect the net prices paid by the Ministry of Health and Long-Term Care under product listing agreements with manufacturers.
2. Figures also include claims submitted for the Special Drugs Program, except those submitted manually.

Note: Manufacturer names are based on the most recent product ownership information submitted by the manufacturer. This information is not intended to reflect ownership changes due to corporate restructuring, mergers and acquisitions, or ownership changes of drug products not submitted to the Ministry.

Pricing of Drugs under the Ontario Drug Benefit Program

One of the factors involved in the decision to fund a drug is its affordability. This includes consideration of the drug price, and the Ministry must determine how much it reimburses pharmacies for the drugs. The Ministry negotiates drug prices with the manufacturers, but it does not buy the drugs directly from the manufacturers. Rather, retail pharmacies purchase drugs through wholesalers, or directly from the manufacturers, and the Ministry pays the pharmacies for the drugs dispensed. The Ministry publishes the price for reimbursement to pharmacies in the Formulary (known as the Formulary price).

Pricing of drugs differs depending on whether the drug is a brand-name (discussed in **Section 4.1**) or a generic drug (discussed in **Section 4.2**).

Brand-Name Drug Prices and Rebates from the Drug Manufacturers

On a quarterly or annual basis, the drug manufacturers rebate to the Ministry a portion of the total price according to agreements they negotiate with the Ministry. These rebates are usually based on volume sold. The net cost (total paid minus rebate) of a drug is confidential and not reported to the public, as the Ministry is contractually barred from disclosing these rebates. (We discuss this further in **Section 4.1**.)

Over the last 10 years, the Ministry has taken a number of initiatives on brand-name drugs. The 2006 reforms to the Ontario Drug Benefit Program provided the Executive Officer of the Program with the ability to negotiate confidential product listing agreements with drug manufacturers. Product listing agreements can incorporate different parameters, such as volume discounts (rebates) where a confidential price is negotiated; reduced Formulary prices; risk sharing with expenditure caps (where the Ministry pays for no more than an agreed-upon volume and the drug manufacturer pays the rest); the drug manufacturer's commitment to promote appropriate use; and the requirement to collect outcome data for future negotiations.

In 2010, the pan-Canadian Pharmaceutical Alliance (Alliance), originally named the pan-Canadian Pricing Alliance, was established to leverage the collective purchasing power of the provinces and territories in negotiations with drug manufacturers. The Alliance is made up of all 13 provincial and territorial jurisdictions and federal drug plans. Together, they negotiate lower prices than one single jurisdiction could on its own.

Patented Medicine Prices Review Board

The Patented Medicine Prices Review Board (Board) is an independent quasi-judicial body that protects the interests of Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. It does this by reviewing the prices that patentees charge for each individual patented drug product in Canadian markets.

Although the Board has no authority to regulate the prices of generic drugs because most of them do not have a patent, it does, however, conduct some analyses and comparisons of the prices of generic drugs in Canada and other countries (discussed in **Section 4.2**).

Generic Drug Prices

Starting with the 2006 reforms to the Ontario Drug Benefit Program, the Ministry has introduced a number of regulatory changes to reduce the prices of generic drugs it reimburses in Ontario. The following explains pricing for generic drugs in Ontario before and after 2006:

Before 2006: The first generic drug approved for reimbursement was priced at 70% of the reference brand price (that is, the price of the brand-name drug it substitutes for). Generics that were approved as substitutes for the same brand-name drug and entered the market later were priced at 63% of the brand price.

2006 reforms: The price of generic drugs was reduced to 50% of the reference brand price, with some exceptions.

2010 reforms: Generic drug prices were further reduced to 25% of the reference brand price for solid drugs and 35% for liquid drugs (with some exceptions). Other changes benefited private-sector purchasers, such as patients and insurers, by linking the prices they paid for generic drugs to the prices listed in the Formulary.

2013 onwards: The Ministry continued to lower the prices of generic drugs through participating in the pan-Canadian Pharmaceutical Alliance. The Alliance established two major initiatives for generic drugs: reducing the prices of commonly used generic drugs and introducing the Tiered Pricing Framework for new generic drugs. These are both explained in **Section 4.2**.

2.1.3 Ministry Payments to Pharmacies and Other Dispensers

Ministry Payments for Drugs

When a patient receives a drug and/or service covered by the Ontario Drug Benefit Program from a pharmacy, the Ministry reimburses the pharmacy based on the valid claims submitted. In most cases, pharmacies must submit their claims online (through the Health Network System) to the Ministry, and payments are scheduled regularly. For each prescription drug dispensed, the Ministry payment to the pharmacies consists of four components (see **Figure 6** for the price and detailed descriptions).

Ministry's Oversight of Payments to Pharmacies

The Ministry has the mandate to conduct post-payment inspections for any of the over 4,260 entities that dispense drugs. Retail pharmacies, including those that serve long-term-care homes and Homes for Special Care, represent 97% (or 4,135) of these entities. The remainder are dispensing physicians, hospital out-patient dispensaries, and allergy product suppliers.

While the Ministry has oversight responsibility over payments made to pharmacies, the Ontario College of Pharmacists, the regulator of the profession of pharmacy in Ontario, has responsibility over safety, professional practices and accreditation. (Inspections are further discussed in **Sections 4.4** and **4.5**.)

Ministry Payments for MedsCheck and Other Professional Services

In addition to the $5.9 billion (2016/17) it spends on drugs under the Programs, the Ministry also pays for services pharmacists perform for eligible recipients. In 2016/17, the Ministry spent $83 million for professional pharmacy services, of which the MedsCheck program represented $70 million. The MedsCheck program is available to all Ontarians with a valid health card, who are taking three or more chronic medications or who meet other program criteria. (MedsChecks are further discussed in **Section 4.6**.)

Most Canadian provinces also fund similar medication review programs. We compare these programs in **Appendix 5**.

2.2 Events Subsequent to Our Fieldwork

Since we completed our fieldwork, the Ministry has announced changes and updates to two main areas of interest, as follows. Given the timing of these announcements, they were not included in the scope of this audit.

OHIP+

In the 2017 Budget, the Province announced that starting January 1, 2018, children and youth aged 24 years and under who are OHIP insured will be able to get eligible prescription medications at no cost. Coverage will be automatic, with no upfront

Figure 6: Components of Ministry Payments to Pharmacies for Drugs Dispensed under the Ontario Drug Benefit Program

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

Ministry Payment	Price	Description
Add # 1, 2 and 3		
1. Drug benefit price	• Prices are listed in the Formulary. The Formulary is the listing that includes all drugs covered for funding under the Ontario Drug Benefit Program, except for drugs funded under the Exceptional Access Program.	• For brand-name drugs, the prices are set based on manufacturer submissions and any negotiations between the Ministry of Health and Long-Term Care and the drug manufacturers. These are stipulated under various product listing agreements.
2. Mark-up	• 8% of the drug benefit price; or • 6% of the drug benefit price for claims with drug costs equal to or greater than $1,000.	• Mark-up costs are intended to cover distribution and inventory costs incurred by pharmacies. • Mark-up costs are set by regulation.
3. Dispensing fee and any applicable compounding fee	• For individuals eligible under the Ontario Drug Benefit Program, the dispensing fee is set at $8.83 for each claim filled. • The dispensing fee can be up to $13.25 where there are few or no pharmacies nearby (e.g., rural areas). • The dispensing fees for drugs not covered by the Ontario Drug Benefit Program are set by the individual pharmacy, and not by regulation.	• Dispensing fees cover services such as general operating costs (e.g., employee salaries and rent), stocking medication, maintaining medical records and sharing them with the physician, and counselling patients on their drug treatment. • Dispensing fees covered under Ontario Drug Benefits Program are prescribed by regulation. • Compound fees are paid at an established rate and by the time spent mixing and preparing the drug.
Deduct # 4		
4. Deductible or co-payment	**Deductibles** • For seniors over the age of 65, $0 or $100 per person per year depending on household income. • For Trillium Drug Program recipients, the deductible is income-based. **Co-payments** • $2.00 to $6.11 per prescription depending on household income and eligible categories.	• Paid by recipients to the pharmacies where the drugs were dispensed. • Deductibles and co-payments are set by regulation.

costs. As what is called OHIP+ creates a new eligibility stream under the Ontario Drug Benefit Program, coverage will include all Ontario Drug Benefit Program benefits, including the cost of the drug products that are currently available on the Formulary. The Province estimated that the incremental investment needed to implement OHIP+ will be about $465 million annually.

Opioids

In August 2017, the Province announced $222 million in new investments over three years to enhance Ontario's Strategy to Prevent Opioid Addiction and Overdose. Among other things, the new investments include an expansion of the supply of an overdose-reversal drug through emergency departments, and an expansion of harm-reduction services, such as needle exchange programs and supervised injection sites. We discuss opioid overdoses in **Section 4.8**.

3.0 Audit Objective and Scope

The objective of our audit was to assess whether the Ministry of Health and Long-Term Care (Ministry) had effective systems and procedures in place to ensure that:

- eligible recipients have timely access to appropriate, up-to-date and cost-effective drugs and pharmacy services;
- payments to pharmacies and other dispensers are in accordance with legislation and agreements;
- drug pricing and procurements in the public sector are reviewed to ensure cost savings are maximized in the province; and
- accurate and complete data on the effectiveness of the Ministry's drug programs is collected, analyzed, used for decision-making and program improvements, and publicly reported, for the benefit of Ontarians.

In planning for our work, we identified the audit criteria we would use to address our audit objective (see **Appendix 6** for criteria). These criteria were established based on a review of applicable legislation, policies and procedures, internal and external studies, and best practices. Senior Ministry management reviewed and agreed with the suitability of our objectives and associated criteria.

We conducted our audit between December 2016 and June 2017. We obtained written representation from the Ministry management that, effective November 14, 2017, it has provided us with all the information it was aware of that could significantly affect the findings or the conclusion of this report.

Our audit work was conducted at the Ministry's Ontario Public Drug Programs Division in Toronto. In conducting our audit, we reviewed relevant documents, analyzed information, interviewed appropriate Ministry staff, and reviewed relevant research from Ontario and other Canadian provinces, as well as jurisdictions in other countries. The majority of our file review went back three to five years, with some trend analysis going back as far as 10 years.

We also reviewed data from the Ministry's Health Network System, which contains claims paid to pharmacies for dispensed drugs and professional pharmacy services in Ontario. As part of the annual audit of financial statements performed by our Office on the Public Accounts of Ontario, we tested key application controls and information technology general controls in the Ministry's Health Network System. We considered the results from that annual financial-statement audit in determining the scope of this value-for-money audit.

We met with a representative of the Ontario Drug Policy Research Network, which is composed of researchers from across Ontario and guides and informs policy makers in making their decisions, and we relied on some of the data analyses it performed.

In addition, we talked to representatives from stakeholder groups, including the Ontario College of Pharmacists, the Ontario Pharmacists Association, and the Ontario Hospital Association. We met with representatives from the pan-Canadian Pharmaceutical Alliance, which collectively negotiates on behalf of all Canadian provinces, territories and the federal drug plans, to gain an understanding of how drug prices are negotiated with drug manufacturers.

In an effort to better understand the drug evaluation process, we attended a Committee to Evaluate Drugs meeting to observe the process of how new drug products are recommended to be funded in Ontario. We talked to the Patented Medicine Prices Review Board to understand how the price of brand-name drugs is regulated in Canada, and we spoke with the group-purchasing organizations that procure drugs on behalf of most hospitals in Ontario. We contacted a sample of hospitals and obtained select generic drug prices to compare to the Ministry's Formulary prices. In addition, we

engaged an expert in pharmaceutical policy with knowledge of drug pricing to advise us.

We attended a site visit to a pharmacy that the Ministry was inspecting as part of its inspection process to gain an understanding of how claims are selected for inspection and how inspectors conduct their inspections. We also met with the Health Fraud Unit of the Ontario Provincial Police to discuss their concerns over how pharmacies are referred to them for investigation of fraudulent billing activity.

We did not rely on the work of internal audit, as it has not conducted any recent work related to the Ontario Public Drug Programs.

We did not compare the prices of brand-name drugs paid by Ontario to other jurisdictions, as the net-of-rebate drug prices in other jurisdictions are confidential and not available for our review. Similarly, we did not compare the prices of brand-name drugs paid by Ontario to the amount paid by hospitals, as the net-of-rebate drug prices of hospitals are bound by the confidentiality agreements between the group purchasing organizations and drug manufacturers.

Finally, we considered the relevant issues reported in our 2007 audit related to the then Ontario Drug Programs Branch (see the section entitled "Drug Programs Activity" in our 2007 Annual Report) and incorporated them into our audit work.

4.0 Detailed Audit Observations

4.1 Rebates on Brand-Name Drugs Have Increased but Price Comparisons Are Difficult

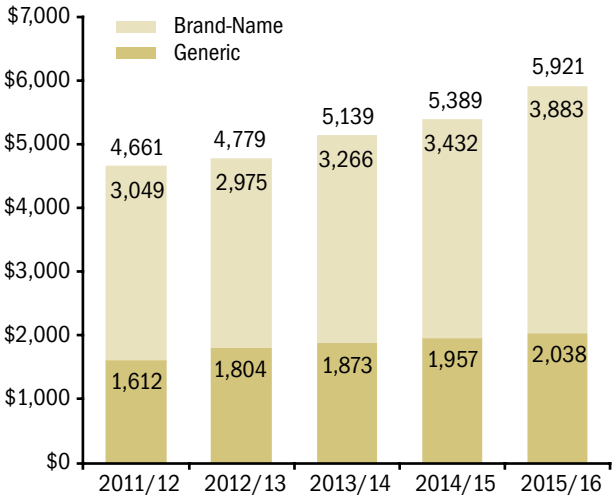
4.1.1 Pricing Reform Has Led to Significant Rebates but Price Comparison to Other Jurisdictions Is Limited

In 2015/16, of the $5.9 billion total expenditures of the Ontario Public Drug Programs (Programs), $3.9 billion, or 66%, was for brand-name drugs, even though they accounted for only one-third of total claims by volume. **Figure 7** shows the breakdown of expenditures between brand-name and generic drugs from 2011/12 to 2015/16.

Over the last 10 years, the Ministry has taken a number of initiatives on brand-name drugs. Most notably, the pricing reforms in 2006 contributed to the Ministry obtaining significant rebates on their

Figure 7: Breakdown of Expenditures* between Brand-Name and Generic Drugs, 2011/12–2015/16 ($ million)

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



* Amounts include expenditures from the Ontario Drug Benefit Program, and include drug cost, markups, dispensing and compounding fees, without netting out recipient co-payments and deductibles. Drug costs are based on the manufacturers' publicly available list price and do not reflect the net prices paid by the Ministry of Health and Long-Term Care after rebates under the product listing agreements with the manufacturers.

price. Between 2006/07 and 2016/17, these rebates grew from $31 million to $1.1 billion. For 2016/17, the total rebate received is close to 30% of the total expenditures for brand-name drugs.

From 2009/10 to 2015/16, a total of 188 product listing agreements have been established with drug manufacturers for drugs listed on the Formulary, and about half of these agreements (96) have rebates associated with them. The rebates negotiated relate to 781 drugs in various strengths and dosages, which include 1,417 out of the approximately 4,400 individual products listed on the Formulary. Many of the drugs that do not have rebates associated with them were added to the Formulary earlier than 2006/07, before the Ministry had the authority to negotiate rebates with drug manufacturers. The Ministry will have to continue to monitor the trends in development of high-cost breakthrough drugs and in rebates to ensure that its negotiating strategy produces cost-effective results for Ontarians as the structure of the drug market evolves.

Relevant Price Comparisons to Other Jurisdictions Is Limited Because of Confidentiality Agreements

Ontario's rebates began to grow significantly in 2012/13 after the pan-Canadian Pharmaceutical Alliance (Alliance) became more involved in negotiating collectively. As mentioned earlier, brand-name drugs are the main cost drivers in Ontario, making up 66% of all drug costs funded under the Ontario Drug Benefit Program. However, despite these rebates, it is unknown whether the Ministry is obtaining reasonable prices for brand-name drugs compared to other countries, due to the contractual obligation that prevents the negotiating parties from disclosing the net cost of a drug. Negotiating confidential rebates on brand-name drugs is a common practice internationally, and therefore there is no benchmark to compare net prices for brand-name drugs across the world.

The Patented Medicine Prices Review Board (Board; see **Section 2.1.2**) is currently updating its guidelines on how the prices of brand-name drugs are regulated to ensure that prices are not excessive. Part of the reason for the update is the growing discrepancy between public list prices and lower actual market prices due to the increased use of confidential discounts and rebates globally. One of the proposed changes to the regulations includes requiring patent holders to provide the Board with information related to rebates and discounts they give other purchasers in Canada. The Board would keep this information confidential, but would use it to better evaluate whether the prices of patented drugs in Canada are excessive. These changes are expected in 2019.

4.1.2 Processing of Drug Rebates Is Too Slow and Prone to Error

While the amount of rebates on brand-name drugs continues to grow, room for improvement exists in the administrative process to ensure the timely and accurate processing of rebates due from drug manufacturers. On average, it takes the Ministry over six months from when rebates are due to invoice drug manufacturers. In one case, it took the Ministry close to nine months to invoice the manufacturers concerned. Given the significant dollar value of rebates ($1.1 billion in 2016/17), we would expect the Ministry to be efficient in processing rebates. Based on a sample of nine manufacturers' invoices representing about $700 million in rebates for a 12-month period, and using the Province's average liquid reserve investment return for 2016/17, six months of lost interest income would equate to about $2.2 million.

Further, we noted that the Ministry's current process of manually calculating rebates for over 90 drug manufacturers and over 1,400 unique drug products is prone to error. We noted that the Ministry has made some errors, totalling over $16 million, in calculating the rebates over the five years from 2012/13 to 2016/17. In one case, a drug manufacturer brought to the Ministry's attention that over $10.2 million had not been invoiced.

Subsequently, the Ministry recovered the amount from the drug manufacturer. When we asked the Ministry for its formal policies and procedures surrounding the rebate process, it informed us that it was in the process of making improvements and formally documenting its processes.

Lastly, while the amount of confidential rebates received from drug manufacturers has grown substantially over the last 10 years, the resources allocated to handle the administration of these rebates have remained comparatively small. In addition, the Ministry informed us that the size, number and complexity of agreements have significantly affected the processing of rebates in recent years. While some rebates are relatively simple (such as volume discount), some may involve complex risk-sharing arrangements that may involve multiple manufacturers and timeframes. As a result, some delays are due to manufacturers disputing amounts and/or requesting data from the Ministry to recalculate the rebate independently.

RECOMMENDATION 1

To help ensure timeliness and accuracy of the rebates received from drug manufacturers, we recommend that the Ministry of Health and Long-Term Care:

- establish and monitor adherence to formal policies and procedures governing the rebate process; and
- review rebate processing data to identify and address areas of delay to ensure greater efficiency, including better allocation of staff resources.

MINISTRY RESPONSE

The Ministry supports this recommendation, as it is important to provide operational excellence and efficiencies. The Ministry recognizes that the value and complexities of the rebates has risen in recent years and is dedicating additional resources (such as staffing) to formalize procedures and to ensure timely invoicing and remittance. In 2016/17, additional staff were added and a dedicated team created to provide greater capacity to support the negotiations and contract management, including reconciliation activities. The reconciliation process is also under review to identify opportunities for streamlining and/or automation to reduce the time to complete the process. As changes are implemented, policy and procedure documentation will be updated.

4.2 Generic Drug Prices Have Dropped Significantly but Ontario Still Pays More than Other Public Payers

4.2.1 Despite Significant Reforms Generic Drug Prices Are Still Higher in Ontario and Nationally than in Other Countries

While the total cost of generic drugs (about $2 billion, **Figure 7**) represented about one-third of the total drug cost in 2015/16, the number of claims for generic drugs accounted for a bigger volume—roughly two-thirds of total claims under the Ontario Drug Benefit Program.

Our audit found that the Ministry has made significant progress in reducing the prices of generic drugs in the last 10 years; however, there is further room for price reductions. Prices of generic drugs continue to be higher in Ontario and nationally than in seven other reference countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States). This was especially true for generic drugs that entered through the pan-Canadian Tiered Pricing Framework (explained in the following sections). As of March 2015, the median foreign prices for these drugs were still 28% below Canadian prices, despite the impact of a weaker Canadian dollar. We observed that a contributing factor to the difference between the Ontario Public Drug Programs, like all Canadian public drug programs, and some other countries was the lack of a competitive tendering process for generic drugs in Ontario.

In **Section 2.1.2**, we described the regulatory changes that have steadily reduced the prices of generic drugs the Ministry reimburses, beginning in 2006. From 2013 onwards, the Ministry continued to lower the prices of generic drugs through participating in the pan-Canadian Pharmaceutical Alliance (Alliance). The Alliance established two major initiatives for generic drugs: reducing the prices of highly used generic drugs and introducing the Tiered Pricing Framework for new generic drugs; we describe both in the following sections.

Price Initiative for Highly Used Generic Drugs

In April 2013, the Ministry and its Canadian partners lowered the prices of six highly used generic drugs to 18% of the reference brand price through the Pan-Canadian Generic Value Price Initiative (Initiative). The Initiative is a joint approach that leverages the combined purchasing power of all provinces and territories (with the exception of Quebec) to obtain lower prices for generic drugs. Before the Initiative came into operation, provinces and territories were paying between 25% and 40% of the reference brand price for these generic drugs.

From April 2014 to April 2016, the Ministry lowered the price of an additional 12 drugs, which brought the total number of highly used drugs priced at 18% of the reference brand price from six up to 18. In April 2017, the Ministry entered into a one-year bridging agreement for the Initiative with the Canadian Generic Pharmaceutical Association to allow time to evaluate the Initiative and determine next steps. The Canadian Generic Pharmaceutical Association represents a group of drug manufacturers that specialize in the production of generic drugs. The bridging period further reduced the prices of six of the 18 highly used drugs from 18% to 15% of the reference brand price.

While the Ministry indicated that the Initiative resulted in substantial savings, we found that there was room for still lower prices for the 18 highly used generic drugs priced at 18% of the reference brand price. An analysis performed by the Patented Medicine Prices Review Board (Board) in 2016 showed that Canadian prices for these drugs dropped 65% between 2007 and 2015, but as of March 2015 average and median prices in the seven reference countries were still 7% and 28% below Canadian prices, respectively. Due to timing, the Board's analysis did not take into consideration the six highly used generic drugs that are now priced at 15% of the reference brand price.

At the time of this audit, the Ministry was negotiating the Initiative (and the Tiered Pricing Framework discussed in the following section) with the Canadian Generic Pharmaceutical Association. Because the negotiations were ongoing, the Ministry could not disclose any additional details.

Tiered Pricing Framework for New Generic Drugs

In November 2014, the Ministry published an invitation to comment on a proposal made by the Canadian Generic Pharmaceutical Association to establish a tiered pricing framework for generic drugs other than the specified highly used drugs. The pricing framework at the time required generic prices to be 25% of the reference brand price for solid drugs and 35% for liquid drugs, with some exceptions. The proposed framework works as follows and is summarized in **Figure 8**:

- Where there are no other generic drugs listed in the Formulary and/or available on the Canadian market (single source generic drug), the price would be set at 85% of the reference brand price, or 75% if Ontario or another Canadian province or territory has a product listing agreement with the reference brand drug.
- Where there are only two generic products available (dual source generic drug) on the Canadian market, the price would be set at 50% of the reference brand price.
- If there are three or more generic drugs, the previous 25% and 35% price rules apply.

The Ministry, as part of the pan-Canadian Pharmaceutical Alliance Generics Agreement, implemented the Tiered Pricing Framework and amended a regulation of the *Ontario Drug Benefit*

Figure 8: The Ministry of Health and Long-Term Care's Tiered-Pricing Framework for Generic Drugs, Effective April 1, 2013

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

# of Available Generic Drugs Equivalent to the Brand-Name Drug	Generic Price (% of Brand-Name Drug Price)
1 (and no other province has a pricing agreement for the equivalent brand-name drug)	85
1	75
2	50
3 or more	25 (for oral solid/pills) 35 (for liquids, patches, injectables, inhalers, etc.)

Act in May 2015. The Tiered Pricing Framework applied retroactively to drugs listed on the Formulary on or after April 1, 2013.

Unlike the Initiative, which saw 18 generic drugs fall to 18% of the reference brand price, the Tiered Pricing Framework allowed the drug manufacturers of single and dual source generic drugs to set higher prices (50%, 75% or 85% of reference brand price) than allowed under the pricing framework introduced as part of the 2010 drug reforms (25% of reference brand price). The previous pricing framework allowed the Executive Officer to consider exceptions, however, which would have resulted in some generic drugs bringing in a higher price than normally allowed.

We also noted that the prices of generic drugs entering through the Tiered Pricing Framework are higher than the prices paid in other countries. An analysis in 2016 by the Patented Medicine Prices Review Board noted that Canadian prices for these drugs fell by 45% between 2007 and 2015, but that prices in the seven reference countries were still 16% and 28% below Canadian average and median prices, respectively, as of March 2015. This large gap indicates room for additional price improvement for generic drugs that entered through the Tiered Pricing Framework.

One criticism we have made of the Tiered Pricing Framework is that it may incentivize drug manufacturers to concentrate their efforts on the single and dual source categories, which allow for higher prices and thus additional costs to the Ministry. The Ministry did not break out the amount of total drug expenditures that related to these categories at the provincial level, as the relative growth in these categories since the introduction of the Tiered Pricing Framework and number of generic drugs in these categories are tracked nationally.

In addition, at the time of this audit, the Ministry had not addressed potential opportunities for additional value from prices of older generic drugs listed in the Formulary before April 1, 2013, which were neither part of the Initiative (described in the previous section) nor the Tiered Pricing Framework. The Ministry could not comment on whether it would address the prices of these older drugs in its current discussions with the Canadian Generic Pharmaceutical Association.

It is important to note that we do not view price as the singular measure of value in our analysis of the Tiered Pricing Framework. We do acknowledge that there are several potential benefits to the Tiered Pricing Framework, such as increased transparency in pricing policy, and better stability and predictability in the generic marketplace to assist drug manufacturers in planning the entry of generics into Ontario. Facilitating entry into the market will result in some cost savings, as generic medicines cost a fraction of their brand-name counterparts. Furthermore, other pricing models such as tendering may result in fewer generic suppliers and a higher risk of drug shortages that could negatively impact patient access to care.

$1.5 Billion Agreement between Quebec and the Canadian Generic Pharmaceutical Association

At the time of this audit, the Government of Quebec and the Canadian Generic Pharmaceutical Association had reached an agreement in principle that will provide the Government of Quebec with targeted savings of $1.5 billion over a five-year term starting October 1, 2017. The targeted savings will come through discounts on existing generic drugs and the launch of new generic drugs. In return for these savings, Quebec will agree not to tender competitively for generic drugs over the five-year term of the agreement. The parties were finalizing the agreement at the time of our audit, and the details were not available publicly.

This agreement in principle provides further evidence that prices of generic drugs in Canada can still reach lower levels. The regulations in Quebec require that generic prices are set according to the best prices granted to all provincial drug plans. As a result, if Quebec can obtain further discounts on these prices, it follows that other provinces and territories can obtain lower prices. However, these discounts came at the cost of agreeing not to tender for generic drugs. The Ministry will have to assess carefully whether a similar deal would be more cost-effective than tendering.

Comparison with Foreign Countries' Generic Drug Prices

We noted that some countries, such as New Zealand and the United States, pay lower prices for some generic drugs than the Ontario Drug Benefit Program. In comparing 20 generic drugs on Ontario's Formulary, our analysis showed that in 2016/17 Ontario paid roughly $100 million (or about 70%) more for the same drugs of the same strengths than New Zealand. The drugs we used in our sample were highly used in the Ontario Drug Benefit Program and also found on New Zealand's formulary. (Industry experts acknowledge New Zealand's generic drug prices to be among the lowest internationally.)

In comparing Ontario to the United States, we noted that the U.S. government-run Medicare and Medicaid programs are similar to the Ontario Drug Benefit Program because they provide drug coverage for seniors and for people with disabilities or low incomes. However, because Medicare and Medicaid recipients are much more numerous than Ontario Drug Benefit Program recipients, we did not compare those programs' formulary prices to the prices of drugs funded in Ontario. Instead, we used the formulary prices from the U.S. Department of Veterans Affairs to do our comparison. (This department's drug program provides federal drug benefits to eligible veterans and uses competitive tenders for its generic drug supply.)

Of the 20 generic drugs that we sampled from New Zealand's formulary, we found that two were not funded by the U.S. Department of Veterans Affairs. Of the remaining 18 drugs, we found that 17 were priced lower than Ontario's prices; the price of the one remaining drug was higher than Ontario's price. One of the 17 drugs was delisted by the Ministry in January 2017 as part of its initiative to address the opioid crisis.

However, we compare Ontario prices to other countries with caution, because it is important to note that drug plans operate in very different environments with regard to, for example, populations, demographics and illness profiles. Also, although some countries may obtain lower drug prices, they may do so at the expense of other possible benefits. For example, New Zealand's decisions not to fund particular drugs have often been controversial, and critics argue that it puts more focus on drug prices and financial implications than evidence-based medicine and good patient care. Further, New Zealand has increasingly experienced drug supply shortages, which is a risk when one drug manufacturer is granted exclusive rights to be the sole supplier of a drug.

4.2.2 Some Ontario Hospitals Pay Less for a Number of Common Generic Drugs Reimbursed under the Ontario Public Drug Programs

We found that some Ontario hospitals paid on average 85% less than the Ontario Public Drug Programs for a sample of generic drugs and noted different prices for the same drugs, even though the purchases in both cases are publicly funded. This inconsistency is due to the different procurement methods and different market characteristics in both settings. While the Ministry follows the Initiative and Tiered Pricing Framework (described in **Section 4.2.1**), hospitals typically use group purchasing organizations to tender bids for drug products on their behalf. The prices obtained by group purchasing organizations are also available to all other hospitals that are members of these organizations.

Hospitals' Competitive Procurement versus Ministry's Generic Drug Framework

Group purchasing organizations use a competitive procurement process to purchase generic drugs on behalf of hospitals. Under this system, drug manufacturers bid on supplying the hospitals' generic drugs, and the winning bid gets the contract. This kind of open competitive procurement process is required by Ontario's Broader Public Sector Procurement Directive, which applies to hospitals and other designated organizations, under section 12 of the *Broader Public Sector Accountability Act, 2010*. Bids are evaluated on a matrix showing price, volume to be supplied, and all other relevant factors. This differs from the Ministry's generic drug framework (**Figure 8**), where prices for generic drugs are set at a given percentage of the prices of the equivalent brand-name drugs.

These group purchasing organizations also negotiate confidential volume rebates for generic drugs, although the Ministry typically does not negotiate volume rebates for generic drugs.

Hospital Needs versus Community Needs

Hospitals often use different drugs than the ones covered by the Ontario Drug Benefit Program for use in the community—for example, certain cancer drugs and drugs used during surgery. However, some drugs are used in both settings. We compared a sample of generic drugs that were used in both the community setting and hospital settings, and found that hospitals were obtaining lower prices by 85%. That means hospitals are paying 15% of the Formulary price. For those drugs that we compared, Ontario Public Drug Programs paid $271 million more in 2016/17 for the same drugs of the same strengths than the hospitals.

To date, neither the Ministry nor the hospitals have completed any analysis or review comparing the procurement practices in both settings to determine if cost savings in the Province could be maximized if the Ministry used competitive procurement for drugs.

The Pharmacy and Therapeutics Committee, or equivalent, at each hospital evaluates drug therapies for addition to or removal from the hospital formulary and in establishing medication-use policies and procedures. These committees consist of individuals with backgrounds in medicine, nursing and pharmacy, and operate under the mandate of hospital accreditation standards.

Prospects for Competitive Tendering for Generic Drugs in Ontario

In spite of the price advantages we have noted with competitive tendering for generic drugs used in other countries and Ontario hospitals, there is no guarantee that Ontario could obtain the same prices for the same drugs under a similar system. For example, it is unknown what factors (such as volume) a drug manufacturer considers when submitting an offer to other countries. Furthermore, a caution is in order. New Zealand and the United States both award exclusive supply rights to one or more manufacturers that offer the most competitive deal. Yet drug shortages that could negatively impact patient access to care are a significant risk

when only one supplier or a few suppliers are allowed to control supply, as has been observed in New Zealand.

We note that the Ministry and Ontario hospitals must consider the consequences of drug shortages and drug supply on patient care under competitive tendering systems. We also note, however, that the Ministry has not conducted an analysis of the ways that other countries and Ontario hospitals pay for generic drugs so that the Ministry could incorporate their best practices in its drug programs.

RECOMMENDATION 2

To help Ontario obtain lower prices for generic drugs from drug manufacturers, we recommend that the Ministry of Health and Long-Term Care:

- conduct a cost/benefit analysis to determine whether best practices (such as tendering) used in other jurisdictions and in some Ontario hospitals could be more advantageous in some circumstances than retaining the Tiered Pricing Framework; and
- collaborate with other jurisdictions through the pan-Canadian Pharmaceutical Alliance to explore ways to negotiate a better Tiered Pricing Framework for generic drugs.

MINISTRY RESPONSE

The Ministry supports this recommendation as it is important to regularly explore other pricing models that may bring additional value. Pricing models in one jurisdiction may or may not be suitable in another jurisdiction, due to a variety of factors, and each model has its advantages and disadvantages that need to be analyzed and considered. It should be noted that the Ministry previously went forward with a competitive tendering process in 2008 that was not successful in achieving a savings model for generic drugs. Work is underway through the pan-Canadian Pharmaceutical Alliance (pCPA) to explore models of pricing generic drugs across all participating jurisdictions in a consistent and predictable manner. The pCPA is currently engaged with the generic industry to achieve further savings and additional value.

4.3 Access to Most Drugs Is Timely but Delays Are Incurred for Exceptional Access Cases

One of the key mandates of the Ministry is to ensure that eligible recipients of drugs through the Programs have timely access to drugs when needed. We noted that the Ministry is able to fulfill this mandate for the majority of recipients when their prescribed drugs are listed on the Formulary. We also reviewed the Ministry's process for listing and funding new drugs and found that it was based on clinical evidence and cost-effective analysis, as described in the following subsection.

Listing/Funding New Drugs in the Formulary

For a drug to be listed on the provincial Formulary, it must first be approved for sale by Health Canada. The Ontario Public Drug Programs do not cover all drugs approved for sale because the Ministry has to balance the needs of Ontarians, the costs of drugs, the evidence of their efficacy compared to other available funded options, and financial considerations including sustainability of the Programs. For that reason, patented drugs (brand-name drugs) go through the pan-Canadian process to inform jurisdictional decision-making before approval for coverage under the Ontario Drug Benefit Program, as shown in **Appendix 7**. In addition, based on the evidence review by the Canadian Agency for Drugs and Technologies in Health or the Ministry's Committee to Evaluate Drugs, some drugs may be more appropriately funded under the Exceptional Access Program (see **Section 2.1.1**) instead of the Formulary, funded subject to other specific criteria, or not funded at all.

Similarly to manufacturers of brand-name drugs, manufacturers of generic drugs must request and receive market authorization from Health Canada. Unlike brand-name drugs, most generic drugs

(about 90–95% of submissions for listing on the Formulary) are not required to be reviewed by the Ministry's Committee to Evaluate Drugs, because they are declared equivalent, by Health Canada's regulatory processes, to the brand-name drugs that have already gone through the approval process. The Executive Officer of the Ontario Public Drug Programs makes the final listing/funding decision.

The Ministry does not regularly delist drugs from the Formulary unless the drug is proven to be harmful or the manufacturer has discontinued production. Before delisting a drug, the Ministry considers the current patient use of that drug so that, for example, no group of patients is left without access to a needed drug or a therapeutic alternative.

4.3.1 Overall Patient Experience Times for Some Exceptional Access Drugs Were Excessive

We noted that some delays (measured in "patient experience time," which we explain later in this section) are incurred when patients require prescribed drugs that are not on the Formulary but are available following case-by-case review through the Ministry's Exceptional Access Program.

The program area receives approximately 24,000 calls per year, or approximately 100 per day, of which the majority, or 88%, are requesting status updates on their requests. A May 2016 survey by Cancer Care Ontario noted that 52 out of 66 (or almost 80%) of oncologists who were surveyed indicated that if there was a delay in receiving a request approval, they would resort to delaying therapy. Other responses from the same group of oncologists surveyed included obtaining a compassionate supply of the drug from the manufacturer (almost 76% of oncologists surveyed said they would do this) and encouraging patients to pay for the prescription themselves (almost 35% of oncologists surveyed said they would do this). Ministry internal documents have also identified inefficiencies in the Exceptional Access Program resulting in delays in processing requests for drugs requiring case-by-case review. **Figure 9** illustrates where some of these delays may occur.

In 2016/17, Ministry costs associated with drugs approved through the Exceptional Access Program were about $810 million for about 65,850 Ontarians who had utilized approximately 580 drugs from the list of over 1,000 drugs requiring case-by-case review to meet approved criteria.

Between 2010/11 and 2015/16, the number of unique requests for exceptional access coverage increased by 26%, from 56,520 to about 71,460. Over the same period, the number of assessment response letters provided by the Ministry to requesting physicians (including those requesting further information) increased by 32%, from about 67,760 to about 89,450.

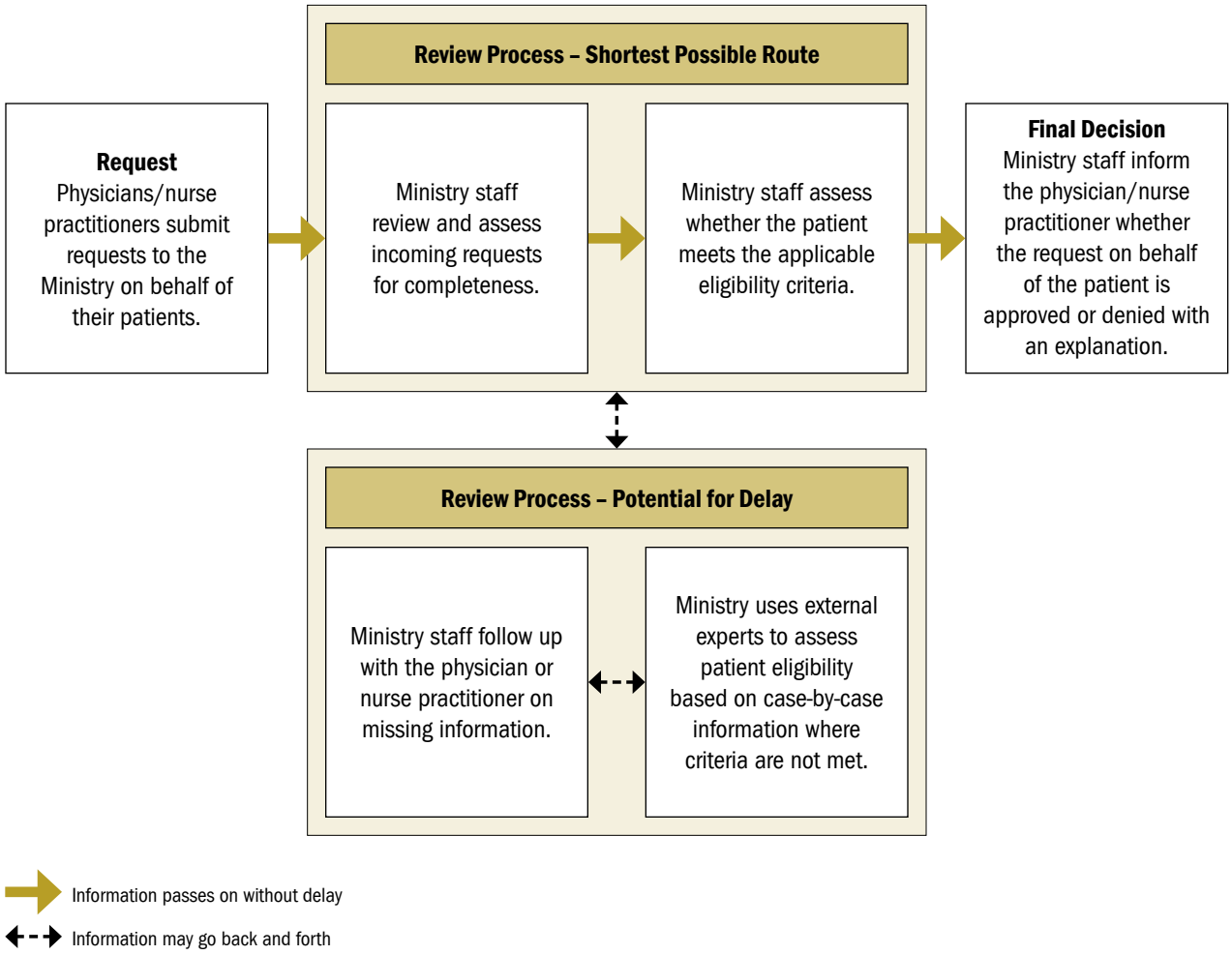
We define "patient experience time" as the time between when the Ministry receives the original request for coverage and when it replies with its decision. The Ministry does not routinely track or publicly report the overall patient experience time for each request, and therefore it does not have a standard or target for meeting patient experience times. However, it calculated these patient experience times at our request.

We found that patient experience times for many requests were too long. For example, in 2016/17:

- The patient experience time taken for the two most requested biologic drugs (3,796 requests for adalimumab and another 4,032 requests for infliximab, both used to treat arthritis, uveitis, inflammatory bowel disease and other conditions) was, on average, between 34 and 41 business days—approximately seven to eight weeks. (Biologic drugs are pharmacological products isolated from natural sources, often using cutting-edge genetic technology.)
- Another 107 requests for a drug to treat gastrointestinal disorders (pinaverium bromide) took on average 59 business days—approximately 12 weeks.

Figure 9: Steps Involved in the Exceptional Access Program

Prepared by the Office of the Auditor General of Ontario



- Another 242 requests for a drug to treat asthma and other indications (budesonide) took on average 57 business days—approximately 11 weeks.
- Another 469 requests for a drug to treat hepatitis C (sofosbuvir) took on average 44 business days—approximately nine weeks—for the Ministry to arrive at a funding decision.

The Ministry noted that the long patient experience times for the two most requested biologic drugs were in part due to about 20% of the requests that were awaiting additional information from physicians, and about 20% that required external review (as illustrated in **Figure 9**). An external review is required for more complex or unique cases. Physicians contracted by the Ministry conduct the review to assess a recipient's unique medical situation against the Ministry's funding criteria.

4.3.2 Ministry Does Not Report Publicly on Actual Patient Experience Time

Instead of reporting the overall patient experience time to the public, the Ministry publicly reports weekly and annually the number of days on average it takes to respond and/or follow up on each piece of missing information from the patients' physicians. The Ministry's rationale for reporting this way (by each response time) was that time spent waiting for missing information is out of its

control; therefore, overall patient experience times should not be used to measure the program's actual performance. The Ministry also indicated that it was unable to track all elements that made up the overall patient experience times. From a patient's point of view, however, it is the time between the patient's appointment with a prescriber, where the need for a drug is identified, and the day the prescriber conveys the Ministry's decision that counts.

However, even when the Ministry measures the time taken based on the number of days that are within its control (that is, by each response time), between 2010/11 and 2015/16 the Ministry consistently failed to meet its targeted times for processing incoming physicians' requests for their patients. **Figure 10** indicates that, for example, in 2015/16, the Ministry was able to respond within its targeted time frames, on average, only 48% of the time, not 85% as targeted.

In 2015/16, about two-thirds of the 89,452 responses were classified in one of the three priority queues that the Ministry targeted for response between three and 10 business days. **Figure 10** shows the percentage of time the Ministry has met its target response times and the average number of days taken for each queue from 2010/11 to 2015/16. The trend indicates that, except for the *non-rush queue*, which is the lowest priority, the average target response times have not been met. On average, the most urgent cases take longer to respond to than less urgent cases. In 2015/16, the Ministry was able to meet its targets only 19% to 36% of the time for urgent cases, compared to 85% for non-urgent cases. We also noted the following:

- Neither the *stat-rush queue* nor the *rush queue* has met its target response time of less than or equal to three days and five days, respectively, in any year.
- The *biologics queue* (which includes only biologic drugs) has met the target response time of less than or equal to 10 days only once, in 2013/14.
- Applications in the *non-rush queue*, which holds the lowest priority cases, have

Figure 10: Ministry of Health and Long-Term Care (Ministry) Response Statistics for the Exceptional Access Program, 2010/11–2015/16[1]

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

	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16
# of Ministry responses (includes approvals, rejections and written requests for additional or missing information)	67,761	71,916	88,158	76,656	75,662	89,452
Priority Queue[2,3] and Target Response Time	**% Meeting Target Response Time (Average # of Business Days before Response Faxed to Requesting Physician)**					
Stat-rush 85% <= 3 days	36% (13 days)	32% (10 days)	40% (6 days)	50% (6 days)	40% (6 days)	36% (7 days)
Rush 85% <= 5 days	13% (32 days)	25% (20 days)	31% (12 days)	56% (9 days)	33% (12 days)	19% (22 days)
Biologics 85% <= 10 days	10% (42 days)	31% (26 days)	66% (12 days)	71% (10 days)	23% (22 days)	30% (23 days)
Non-rush 85% <= 30 days	29% (66 days)	61% (31 days)	84% (20 days)	91% (11 days)	79% (19 days)	85% (17 days)
Total % meeting target (weighted average)	**25%**	**39%**	**58%**	**69%**	**43%**	**48%**

1. Ministry response statistics do not measure the time it takes for a response to a request for drug coverage to be communicated to a physician or nurse practitioner (patient experience time); instead, they measure the time it takes to respond and/or follow up on each piece of missing information in a request. A request with incomplete patient information may require more than one response before the recipient is informed of the Ministry's decision on drug coverage.
2. The allocation of drugs to each queue is based on the drug and the clinical indication(s) for which it is used.
3. The names of the priority queues were revised as of April 1, 2017.

consistently met their target response time of less than or equal to 30 days since 2012/13.

4.3.3 Weaknesses in Processing Exceptional Access Requests Have Been Known Since 2010

The Ministry made proposals to address the program challenges as early as 2010, seven years prior to our audit. A 2010 internal Ministry document stated that an online channel for applications, an interactive voice-response status inquiry, and real-time, online assessment decisions for some drugs would be introduced in the first quarter of 2011/12. However, at the conclusion of the concept phase, those proposals were not approved to proceed. As a result, an information-system solution to address the program challenges was paused at the time. Although the Ministry has tried to address the delays through changes in processing of requests, its response times to exceptional access requests have continued to fall short of its targets.

In 2015, the Ministry proposed a new Special Authorization Digital Information Exchange system and received approval to proceed with the implementation in the following year. Assuming the new system is complete in October 2018, as planned, it will have been three years after it was first proposed in 2015. In August 2016, the Ministry's estimate of the project's total budget was approximately $14.4 million between 2016/17 and 2018/19.

The Special Authorization Digital Information Exchange is expected to transform the ways in which physicians and nurse practitioners interact with the Exceptional Access Program and to streamline the back office processing of requests. Its purpose is to modernize a process that is still largely manual. For example, requests are now received through a telephone request service, by mail or as faxed images, and these must all be manually data-entered into the system. Adjudicating requests and applying eligibility criteria are also done manually.

The new system will also allow the Ministry to aggregate more clinical data, such as what drug each patient is using and for which specific indication, which condition each patient has, which specific criteria are met, which unmet criteria resulted in a rejection of the request, and which drugs required an external review. Given that the Ministry's decisions on exceptional access drugs must balance patient/clinical factors and cost factors, this type of information will allow the Ministry to make better decisions regarding which drugs it should fund only through the Exceptional Access Program or under other specific criteria, instead of as a general benefit on the Formulary.

RECOMMENDATION 3

To help ensure that patients receive timely access to drugs that are considered for coverage under the Exceptional Access Program, we recommend that the Ministry of Health and Long-Term Care:

- streamline the existing processes to consistently meet its targeted response times for all requests for drugs covered through the Exceptional Access Program;
- complete the implementation of the new Special Authorization Digital Information Exchange system; and
- use the new system to collect the necessary data to inform the policies and administration of the programs, such as whether it should fund certain drugs through the Exceptional Access Program, with other specific criteria or as a general benefit through the Formulary.

MINISTRY RESPONSE

The Ministry agrees that Ontarians should receive timely and equitable access to effective therapies and that processes for both access and funding of such therapies should be streamlined, efficient and sustainable to effectively serve the public. The Ministry accepts the recommendation to make process improvements to optimize the timeliness of access

to drugs covered through the Exceptional Access Program.

The Exceptional Access Program currently receives between 250 and 500 requests a day for case-by-case review and continues to modernize and optimize its manual processes for assessment of requests through technology solutions, streamlining initiatives and enhancing criteria transparency. The Special Authorization Digital Information Exchange solution will be launched in 2018, offering an online digital service for prescribers applying to the Exceptional Access Program that has the capability to provide real-time responses for many Exceptional Access Program drugs and indications and to improve the timeliness of decisions for drug access. The Ministry intends to use information from the Special Access Digital Information Exchange for program planning and analytical purposes, including supporting forecasting for ongoing program improvements to meet clinician and patient needs.

4.4 Few Inspections and Lags in Reporting Potential Fraud Have Resulted in No Action Taken in Suspicious Cases

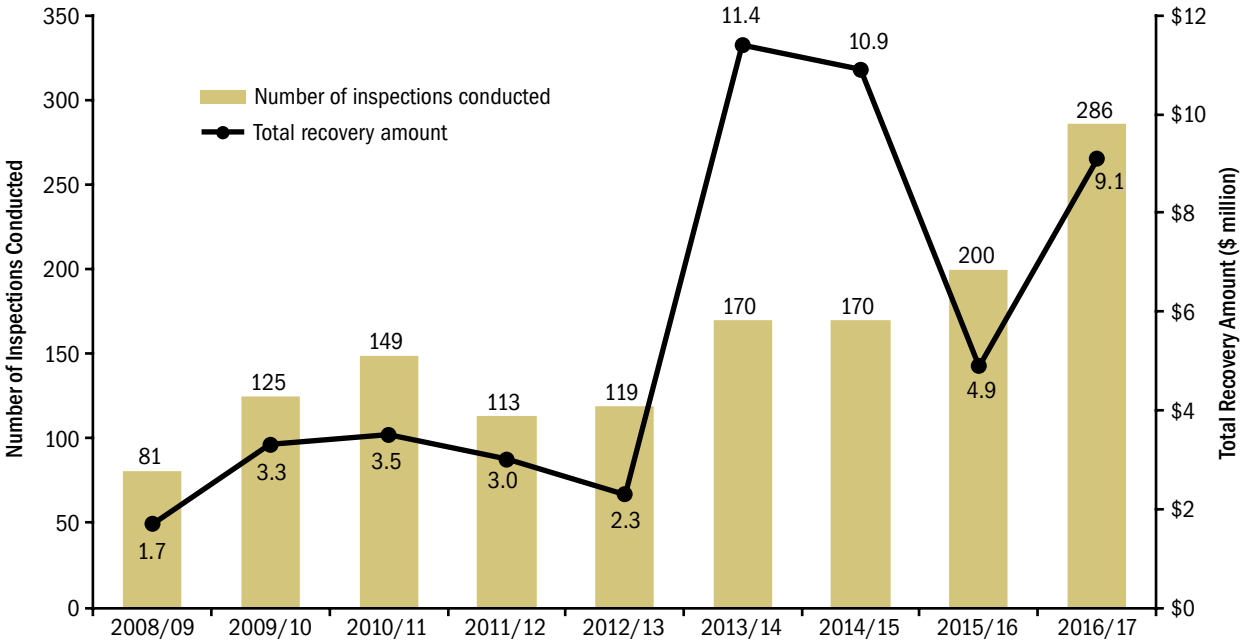
4.4.1 Few Pharmacies Were Inspected

The Ministry oversees payments under the Programs to over 4,260 dispensing entities, including retail pharmacies and retail pharmacies that also serve long-term-care homes. With the staffing resources available at the Ministry, inspecting all these entities would not be possible or practical. Since we identified inspection coverage as an issue in our 2007 value-for-money audit "Drug Programs Activity," we have noted that the number of inspectors has increased, from three in 2006/07 to 10 in 2016/17, and the number of annual inspections has also increased.

Figure 11 shows that the number of inspections increased from 81 in 2008/09 to 286 in 2016/17, and recoveries of inappropriate payments resulting from these inspections increased from $1.7 million

Figure 11: Number of Inspections Conducted and Total Amount Recovered, 2008/09–2015/16

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



Note: The spikes in recoveries for 2013/14 and 2014/15 were attributed to six pharmacies that were inspected and resulted in very high recoveries of $6.5 million in 2013/14 and $5.96 million in 2014/15.

to $9.1 million. We also noted that the number of inspections per inspector increased during the same period—from about 12 annual inspections in 2008/09 to 29 annual inspections in 2016/17.

Despite the increase in pharmacy inspections, we noted that the percentage of pharmacies and other dispensing entities inspected by the Ministry is still low. As of February 1, 2017, there were over 4,260 dispensing entities that could be subject to Ministry inspections. (The number of active pharmacies changes frequently, since pharmacies open and close regularly across Ontario.) Of these, only 19% had been inspected under their current ownership. **Figure 12** shows that since 2008/09, between approximately 2.4% and 6.7% of active dispensing entities have been inspected each year. Also every year, the number of pharmacies grows on average about 3%. At the current inspection rate, each pharmacy or dispensing entity would be inspected once every 15 years, which is an improvement over once every 30 years from the last time we audited the program in 2007, but still a low rate of inspection.

Inspectors' responsibilities include reviewing pharmacy claims data for variances, conducting in-depth inspections where appropriate, and taking action to recover inappropriate payments.

Ministry inspections are typically initiated for any of the following reasons: data mining or analytics performed by inspectors, the anticipated sale or closure of a pharmacy and its account with the Ministry, information from the Ministry's fraud hotline, and tips from the Ministry help line that answers pharmacists' queries. An inspector may examine any pharmacy records in any form in the possession of a pharmacy if the inspector believes that these records will assist in determining the accuracy of a claim for payment.

4.4.2 Ministry Did Not Refer Several Potentially Fraudulent Cases to the Ontario Provincial Police in a Timely Manner

We noted that no formal protocol has been established between the Ministry and the Ontario Provincial Police (OPP) regarding what should be communicated between them, and when, if suspicious claims have been identified as a result of pharmacy inspections. This has resulted in the OPP not investigating some cases because information was not forwarded in a timely manner.

Figure 12: Percentage of Pharmacies and Other Entities Inspected and Number of Cases Referred to Ontario Provincial Police, 2008/09–2016/17
Source of data: Ministry of Health and Long-Term Care

	% of Pharmacies and Other Dispensing Entities Inspected	# of Inspection Cases Referred to Ontario Provincial Police
2008/09	2.4	0
2009/10	3.6	1
2010/11	4.1	5
2011/12	3.0	8
2012/13	3.1	4
2013/14	4.3	0
2014/15	4.2	0
2015/16	4.7	2
2016/17	6.7	13

During the course of an inspection, an inspector may uncover findings that suggest fraudulent claims may have been submitted to the Ontario Public Drug Programs. On a case-by-case basis, management will determine whether the case warrants referral to the OPP so that it can conduct a criminal investigation.

Figure 12 shows that there were no cases referred to the OPP in both 2013/14 and 2014/15, followed by two cases in 2015/16 and 13 in 2016/17. The 13 cases in 2016/17 resulted from a meeting between the OPP and the Ministry in August 2016, where the OPP questioned Ministry staff why few files or none at all were being sent to it for investigation. Soon after, the Ministry forwarded the 13 files to the OPP for further investigation.

We noted that in all of these cases the Ministry terminated the pharmacies' billing accounts and recovered a total of $1.8 million from inspections conducted between 2011 and 2015.

When we spoke to the OPP about the 13 files, we noted that eight of them were too old to investigate, because the inspections had taken place between 3.5 and five years before the date of referral. Representatives from the OPP explained that they were not able to proceed with an investigation on all the files mainly because the Ministry had not sent them in a timely fashion. The length of time since the alleged offence, the lack of available evidence for examination, monies paid back to the Ministry by the pharmacy, and limits on the OPP's resources were the specific reasons for rejecting files for investigation. The Ministry could not explain why these cases had not been forwarded to the OPP in a timely manner.

Although the Ministry terminated the accounts of all these pharmacies, eight were left without further investigation by the OPP even though documentation suggests that fraudulent billing was suspected. For example:

- In all eight cases there were discrepancies between drug purchases and sales where the pharmacy could not explain why there were not sufficient drug inventory purchases to cover the pharmacy's claims to the Ontario Drug Benefits program.
- In three of the eight cases, physicians or patients denied that prescriptions were actually prescribed or received after they were sent verification letters.
- In another case, the inspector noted a concern that during every site visit related to the inspection, the inspector did not see one patient or hear the phone ring.
- One pharmacy owner admitted that when they did not have enough stock to fill a prescription, they gave the patient what was on hand and still billed for the full amount. If the patient subsequently did not pick up the balance of the prescription owing, the pharmacy owner would sometimes return the balance to stock without crediting the claim. This pharmacy owner claimed that the pharmacy was too busy to do the necessary paperwork, and that they did not deliver the balance to the patient because delivery was too expensive.

RECOMMENDATION 4

To help ensure that appropriate and timely action is taken regarding possible fraudulent claims, we recommend that the Ministry of Health and Long-Term Care work with the Ontario Provincial Police to establish and follow a formal protocol identifying criteria and targets for exchanging information in a timely manner.

MINISTRY RESPONSE

The Ministry agrees that the timely acquisition of information by the Ontario Provincial Police (OPP) will aid in more successful investigations into potentially fraudulent activities by pharmacy operators. The Ministry will work with the OPP to establish a formal protocol for information sharing. This will be one component of a risk-based framework for monitoring Ontario Drug Benefit payments to pharmacies.

4.4.3 Many Invalid Claim Payments Were Not Inspected or Recovered

We noted several areas where the Ministry paid invalid claims to pharmacies, yet it did not inspect and/or recover many of these invalid payments, leading to about $3.9 million of inappropriate payments.

Claims Paid for Deceased Patients

Claims are sometimes paid for patients who have died. This may happen, for example, for patients on regular drug schedules in long-term-care homes, if the pharmacist processes a prescription after a patient's recorded date of death. Pharmacies are expected to submit claim reversals in these cases; in many cases, they can return the drugs to their inventory. The Ministry routinely recovers these claims from pharmacies that it has inspected,

because the date of death is captured in the Health Network System. But if there is no inspection, there is often no recovery. In 2015/16, recoveries related to claims paid for deceased patients totalled $42,365, even though the Ministry had paid about $951,900 for their prescriptions. This resulted in about $910,000 not recovered by the Ministry.

Claims Paid for Unsuccessful Reversals of Claims

We noted that claims are paid for prescriptions that pharmacies may subsequently try to reverse online. This sometimes happens because the pharmacies have only seven days to reverse a claim online through the Health Network System if they submitted it inappropriately or erroneously. An example of this is when a pharmacist submits a claim before patients pick up their medication, but in the end the patients never pick it up. After seven days, the reversal does not get processed. (If a reversal is submitted online, after seven days the system sends a response that the claim is too old and directs the pharmacy to submit a paper reversal form.) The system logs claims that were attempted to be reversed and where the pharmacy was directed to submit a manual claim for reversal. When no manual reversal was submitted, inspectors can review and recover these amounts when they inspect pharmacies. Recoveries related to claims for unsuccessful reversals in 2015/16 were about $900,000 for 130 pharmacies, which was 19% of total recoveries that year. The amount the Ministry paid for claims where reversal attempts were unsuccessful was nearly $3.1 million. This resulted in about another $2.1 million not recovered by the Ministry.

We noted that the industry standard for pharmacies billing private insurance companies is 90 days to reverse a claim. If the Ministry also provided pharmacies with a longer time frame to reverse their claims, it would be paying fewer invalid claims.

Claims Paid for Ineligible Recipients on Limited-Use Drugs

We noted that claims are paid for ineligible recipients relating to a category of drugs called limited-use drugs. The drugs in this category are funded only for specific uses, and patients must meet set criteria to be eligible for them. For example, the patient must be of a certain age and/or gender, and/or have a specified medical condition, and/or present specific symptom tests or other laboratory results. Some of these drugs are not prescribed for general use because of their high cost, while others may have adverse side-effects in some patients. Certain limited-use drugs may have recognized benefits for some conditions but may also have the potential for widespread use in treating other conditions.

A physician may have various reasons for prescribing a limited-use drug to treat a patient who does not meet the required criteria for reimbursement. Some physicians may not be concerned that a less expensive alternative to a highly effective drug is available on the Formulary. In other cases, the physician may have been advised that the drug is effective when prescribed for a different condition than the indications specified in the Formulary, and for which the drug is conventionally used.

As of May 31, 2017, the claims submitted for funding under limited-use criteria represented approximately 950 drugs out of 4,400 listed on the Formulary. For 2015/16, total expenditures on limited-use drugs were about $1.3 billion for 1.4 million recipients. In 2015/16, the Ministry recovered about $1.08 million from 148 pharmacies as a result of inspections related to invalid criteria used for prescribing limited-use drugs. Dispensing drugs contrary to the limited-use criteria is the number one reason for recovery from inspections.

We noted that there is often no way for pharmacists to verify whether clinical criteria are met before dispensing a limited-use drug. This is because the Health Network System does not collect clinical data and the physician is not required to provide such information. Although the physician must certify in a “reason for use code” that the

clinical criteria have been met and the pharmacist must inspect the code, if the physician enters an incorrect code, even a pharmacist who properly inspects the documents will often not uncover the error. Without an electronic data system in place and linkages to physicians, the clinical data to inform the pharmacist is not available. Pharmacists are required to use their professional judgment to confirm the patient's eligibility with the physician or with the patient, if possible.

However, clinical criteria relating to the patient's age and gender can be verified prior to payment, since this information is captured on the patient's health card. We obtained claims data for the calendar year 2016 and selected a sample of limited-use drugs with age- and gender-based criteria for analysis, and found that approximately $922,000 was spent where the criteria were not met. For example:

- Two different drugs to treat a skin condition both require the patient to be 18 years or older in order to be reimbursed for the drugs. In 2016, 164 claims were paid for a total of $279,000 where the patient was younger than 18 years.
- Another drug used to treat a bone disease is covered only for women. However, in 2016, approximately 1,100 claims were paid for men for a total of $422,000.

In these two examples, these drugs appear to have been used safely by patients who may be able to benefit from them, even though the patients did not meet the Ministry's limited-use criteria. However, the Ministry did not know why physicians prescribed these drugs and/or whether its criteria for limited use for these drugs are outdated. The Ministry also did not know why pharmacists were not verifying patients' age and gender prior to claiming these drugs.

RECOMMENDATION 5

To help ensure that only valid and appropriate claims are paid to pharmacies, we recommend that the Ministry of Health and Long-Term Care (Ministry):

- recover payments from all pharmacies for claims paid inappropriately for deceased persons and unsuccessful reversals;
- allow pharmacies a longer time frame to reverse invalid claims, in line with the industry standard;
- investigate why some physicians prescribed limited-use drugs to patients who did not meet the Ministry's limited-use criteria and review whether the Ministry's existing criteria are up-to-date; and
- implement system controls to prevent claims that do not adhere to limited-use criteria, such as gender- and age-based criteria, so that these claims would be rejected or adjudicated at the point of dispensing and therefore would not have to be subject to inspection.

MINISTRY RESPONSE

The Ministry strives to ensure that all payments to pharmacies are appropriate and conform to the *Ontario Drug Benefit Act*, other statutes and associated regulations, and Ministry policies. System controls can prevent some amount of inappropriate billing, but the Ministry also relies on the professional standards and ethics of physicians, nurse practitioners and pharmacists, all of which are regulated health-care professions in Ontario.

The Ministry agrees that invalid claims for deceased persons and unsuccessful reversals should be actively recovered where appropriate. The Ministry is enhancing its capacity for reviewing pharmacy billing data through the addition of new assessment staff and implementation of enhanced analytics.

The Ministry is actively reviewing the extension of the current seven-day reversal period placed on the processing of online claims by pharmacies. Extending the window to allow more time for electronic submission through the Health Network System will require a change to a regulation under the *Ontario Drug Benefit Act*.

The Ministry will consider the implementation of system controls and automation for limited-use drugs to enable greater adjudication of limited-use criteria at the points of dispensing. Cost-benefit analysis will need to take into account the benefits of potential claim-processing improvements against the cost that may be incurred to automate through system changes.

4.5 Ministry Could More Effectively Manage Its Oversight of Pharmacy Claims and Payments

4.5.1 Ministry Lacks Detailed Plans and Approach to Inspect Pharmacies

Since inspecting each pharmacy is not practical, it is critical for the Ministry to identify and target high-risk pharmacies where inappropriate billings are occurring and focus inspection resources on these pharmacies. Although the Ministry has prepared plans for pharmacy inspection, we found that the plans provide only general guidelines with a broad direction for inspectors to follow. The plans do not, however, outline high-risk entities with analytics run on a provincial basis. We expected the Ministry to have detailed plans that identify specific risk areas where inspector resources would be focused; however, no such documented plans existed. We also expected to see inspection reports that detailed common themes and areas where pharmacies were making billing mistakes and where pharmacies would benefit from communication from the Ministry on how to bill appropriately. Again, no such analysis existed.

After a pharmacy is inspected, an amount owing to the Ministry is almost always recovered; nevertheless, the Ministry has no plan or focus to follow up on these pharmacies to ensure that identified errors are not repeated. The Ministry told us that data analytics are performed on pharmacies that have recently been inspected to determine whether inappropriate claims are still being submitted. There was no documentation to support this, however.

We asked the Ministry to identify the most common errors resulting in recoveries. Data the Ministry provided indicates that in 2015/16, the most common error resulting in recoveries was prescribing limited-use drugs to patients who did not meet the required criteria for these products, at nearly $1.08 million in recoveries (see **Figure 13**). We discussed this in **Section 4.4.3**.

RECOMMENDATION 6

To help ensure better use of inspectors' resources and that high-risk pharmacies with potentially inappropriate billings are inspected, we recommend that the Ministry of Health and Long-Term Care use detailed annual inspection plans, identify high-risk areas and/or pharmacies, and allocate its inspection resources more robustly based on risk.

MINISTRY RESPONSE

The Ministry agrees that inspection resources could be allocated more effectively with tools that identify high-risk pharmacies and inform detailed annual inspection plans. The Ministry will augment its data analytics capabilities to identify high-risk pharmacies for inspection, develop a framework for detailed annual inspection plans, and allocate inspection resources accordingly.

4.5.2 Inspection Efforts Were Spent on Areas That Could Be Automated

Ministry inspectors may recover amounts paid to pharmacies if the pharmacy does not retain specific required documentation and forms. However, the only way for an inspector to verify missing forms is to conduct a physical inspection at the pharmacy.

The inspectors spend much of their efforts on verifying that these forms exist on the pharmacists' premises. If the prescribing physicians completed and stored the forms relating to their prescriptions electronically with linkage to the inspectors,

Figure 13: Inappropriate/Invalid Pharmacy Claims Resulting in Recoveries, 2015/16

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

Description of Inappropriate/Invalid Claim	# of Pharmacies	Amount Recovered ($ 000)
Invalid criteria for limited-use product[1]	148	1,079
Unsuccessful reversals[2]	130	900
Dispensing less than the quantity claimed, resulting in overpayment[3]	6	596
Missing side-effect reporting forms for adverse reactions[4]	108	498
Invalid MedsCheck claim[5]	99	403
Package size error[6]	76	347
Other[7]	22	320
Missing nutritional products form[8]	61	273
Missing drug benefit eligibility card[9]	60	243
Invalid criterion for nutritional product[10]	54	186

1. A limited-use product is reimbursed only when prescribed for an eligible recipient who meets the required criteria listed in the Drug Benefit Formulary for the product. Patients are eligible only when all specific clinical criteria and/or conditions for use are satisfied.
2. Claims the pharmacist submitted and received payment for, and then tried to reverse (e.g., erroneous or inappropriate claims) online more than seven days after the claim was processed. Claims cannot be reversed online after seven days.
3. Billing for a larger quantity than the quantity actually dispensed. For instance, billing for a three-month supply of a product but dispensing only a one-month supply.
4. Pharmacist's failure to retain a copy of a patient's prescription and/or the Side Effect Reporting Form, completed and signed by the prescriber.
5. Pharmacist's claim paid for MedsCheck services provided to a drug recipient who is ineligible to receive these services, or pharmacist's failure to retain a copy of the recipient's signed medication review list and any supporting documents.
6. Incorrect billing of the quantity of a product. One such error involves billing by volume instead of by number of units.
7. Other errors not falling into the usual categories.
8. Failure of a pharmacy to retain a valid nutritional products form, fully completed and signed by the physician. (See also note 10.)
9. Failure to retain a valid drug benefit eligibility card on the date of patient service.
10. Nutritional products are eligible for coverage only when prescribed by a practitioner as the patient's sole source of nutrition (orally or by tube), and in addition the patient meets specific clinical criteria. Products are reimbursed only when the proper form is retained and all specific clinical criteria and conditions for use are satisfied.

this resource-intensive manual process could be avoided.

Automation could result in better use of inspector time in the following two areas:

Forms for nutritional products: Certain nutritional products (dietary supplements) are eligible for coverage under the Programs, but the pharmacist needs the patient's physician to complete and sign the appropriate form in order to be reimbursed. If the physician has not provided the form, the entire cost of the nutritional product is recoverable by the Ministry upon inspection. In 2015/16, $32.8 million was paid for over 20,000 patients for claims that required nutritional forms. In the same year, the Ministry recovered $273,000 from 61 pharmacies that it inspected.

Forms for side-effect reporting: The Ministry will reimburse a pharmacy only for the cost of the less-expensive generic equivalent of a brand-name drug unless the patient has an adverse side-effect to the generic drug. The pharmacy must have a copy of the appropriate form completed and signed by the patient's physician to be reimbursed for the full cost of the brand-name drug it has dispensed. If the form is not on the pharmacy's premises during an inspection, the Ministry will recover the difference in cost between the generic drug and the brand-name drug. In 2015/16, total claims paid that required these forms were $14.9 million for 26,730 patients. In the same year, the Ministry recovered $498,000 from 108 pharmacies that it inspected.

RECOMMENDATION 7

To improve the use of inspectors' resources with the focus on enforcing that only valid claims are paid, we recommend that the Ministry of Health and Long-Term Care:

- assess whether the required forms relating to prescriptions could be accessed differently; and
- reimburse claims only when the required forms are submitted.

MINISTRY RESPONSE

The Ministry will conduct further analysis to assess both the operational and technical feasibility of this approach and the cost of making changes to receive and store forms for nutritional products and side-effect reporting.

In addition, an evaluation of protocols relating to recovery for claims for which required forms are not submitted will be conducted.

4.6 Effectiveness of MedsCheck Is Still Not Known

4.6.1 MedsCheck Performance Indicators Lacking

A MedsCheck is a one-on-one consultation between a pharmacist and a patient to review the medication profile of a patient who is taking three or more chronic-use medications or meets other criteria for eligibility.

The Ministry set clear objectives for the MedsCheck program, such as promoting healthier patient outcomes, quality of life and disease self-management, and improving patient knowledge, understanding of and adherence to drug therapy. However, it did not identify what information it would need to evaluate whether it was meeting these objectives. As a result, the Ministry could not provide sufficient evidence as to the program's ability to meet its intended goal and objectives in a cost-effective manner. The Ministry also did not establish any performance indicators to measure the success of the program.

The Ministry launched the MedsCheck program in April 2007 as the first professional pharmacy service in Ontario outside of dispensing services. Since the program's inception, from 2008/09 to 2016/17, the Ministry has spent approximately $550 million on MedsCheck services.

MedsCheck came in at a time when Ministry drug reforms had significantly reduced pharmacy revenues by reducing the prices of generic drugs and prohibiting pharmacies from receiving rebates and professional allowances from drug manufacturers. The Ministry estimated these pharmacy rebates and professional allowances to be worth hundreds of millions of dollars. To counteract some of these losses, we observed that the Ministry increased dispensing fees steadily from 2007 onwards and began reimbursing pharmacies for performing professional services such as MedsCheck, administering influenza shots, and identifying drug-related issues when dispensing a medication.

Even taking into consideration the history and context of the launch of reimbursed pharmacy professional services in Ontario, the lack of performance indicators forces us to question the usefulness and effectiveness of a program like MedsCheck. As technology continues to progress, the Ministry will need to evaluate the value of this service and adjust reimbursement accordingly based on evidence. For example, one of the key outcomes of a MedsCheck is a personal medication record that contains a list of all the prescription medicines, over-the-counter drugs, and/or herbal medicines used by a patient.

The Ministry informed us that the program enhancements of October 2016 (discussed in **Section 4.6.2**) were its first steps in attempting to measure MedsCheck's success. The Ministry also indicated that collecting relevant, accurate and complete data was a significant challenge to meet for it to measure the program's effectiveness. Although most Canadian provinces fund medication review programs (**Appendix 5**) that are similar to MedsCheck in Ontario, we did not identify any

other provinces or countries that have implemented performance indicators for their medication review programs.

Based on our research, the following are potential performance indicators and outcomes that could be expected from MedsCheck:

- a reduction in adverse patient events related to the use of multiple medicines;
- a reduction in the number of hospital admissions due to adverse drug events;
- a reduction in the amount of wastage from unnecessary prescription medication; and
- confirmation that those patients who take the most medications are receiving MedsCheck services.

4.6.2 Ministry Implemented Changes to MedsCheck Contributing to Fewer Patients Receiving the Services

We noted that the Ministry implemented changes to the MedsCheck program in October 2016 without adequately assessing the consequences, and as a result, the number of MedsChecks has significantly decreased, contributing to fewer patients receiving the services.

Total expenditures for MedsCheck decreased by 24% in one year, from $92 million in 2015/16 to $70 million in 2016/17. The number of claims also decreased by 25%, from 1.6 million to 1.2 million. We noted that the decrease in MedsCheck services was higher among those patients taking more medications and thus requiring more documentation and longer consultation sessions. The proportion of MedsChecks for patients with three to four medications dropped by 4%, while MedsChecks for patients with more than 13 medications decreased by 9.3%. Given that the Ministry provides a fixed payment of $60 per MedsCheck regardless of patient complexity, pharmacists may have less incentive to seek out and provide these services to patients with more medications and who would benefit more from the MedsCheck service.

In October 2016, the Ministry enhanced the MedsCheck program to increase the quality and consistency of the process. The new process required pharmacies to use standardized forms and provide more documentation when conducting MedsCheck services as a way to measure the program's success. While this enhancement is a positive step, it had the unintended consequence of reducing the number of overall MedsChecks performed by pharmacies because of the increased burden of additional documentation. For example, pharmacists are now required to enter the same patient information on three separate forms, which is redundant for the pharmacist and time-consuming, but necessary for the Ministry to collect important information. At the time the enhancements were launched, most pharmacies' systems did not have the ability to fill in these required fields with previously saved data, so they had to manually enter patient information on each form.

At the time of our audit, the Ministry was consulting with the Ontario Pharmacists Association about when pharmacies would acquire the software required to fill out MedsCheck forms electronically. We understand that most pharmacies are expected to acquire the required software, but an estimated time is not available.

The Ministry's plan is to evaluate the MedsCheck program at a future date when pharmacies' software is compliant with Ministry requirements. The Ministry has engaged a research group and the Ontario Pharmacists Association to develop an evaluation proposal. At the time of our audit, the Ontario Pharmacists Association confirmed that a survey of pharmacy software vendors was in progress to determine pharmacies' software compliance with Ministry requirements.

RECOMMENDATION 8

To help ensure that patients who need MedsCheck services are receiving them and that MedsCheck achieves its intended purposes, such as promoting healthier patient outcomes,

quality of life and disease self-management, we recommend that the Ministry of Health and Long-Term Care:

- develop performance measures and explore an approach to collect, monitor and analyze data to evaluate the program and assess whether or not MedsCheck services are helping to improve patient health outcomes; and
- work together with pharmacies and the Ontario Pharmacists Association to streamline the administrative process to submit MedsCheck claims.

MINISTRY RESPONSE

The Ministry supports the evaluation and monitoring of the MedsCheck program and identification of opportunities to streamline administrative processes for pharmacies to document the MedsCheck program process and outcomes. As of 2007, the submission of MedsCheck claims for payment of professional service fees to pharmacies by the Ministry has been fully automated and facilitated through the pharmacy software.

The Ministry and the Ontario Pharmacists Association (OPA) have engaged researchers to evaluate the program enhancements for the MedsCheck program that were implemented in late 2016. The evaluation will begin in early 2018 and solicit input from patients, prescribers and pharmacists to determine the effectiveness and impact of the changes on all three experiences.

In developing the enhanced MedsCheck program service and claims submission process, the Ministry worked with the pharmacy sector, particularly the OPA, which gave advice including information needed on forms, and liaised with the pharmacy software vendors to update the pharmacy management systems.

4.7 Ministry Pays Ontario Pharmacies Serving Long-Term-Care Homes Significantly More in Dispensing Fees than Other Provinces

Although Ontario pays low dispensing fees compared to the rest of Canada (see **Appendix 8**), we found that the Province pays significantly more to pharmacies that dispense drugs to residents of long-term-care homes than some other provinces.

In 2015/16, the Ministry paid an average $1,818 dispensing fee per recipient to pharmacies for claims submitted for residents of long-term-care homes. This is more than four times higher than the average dispensing fee of $422 for all other recipients over the age of 65. Dispensing fees paid to these pharmacies were about $190 million (out of a total $1.2 billion in 2015/16), covering approximately 105,000 recipients living in long-term-care homes. See **Figure 14** for a comparison of dispensing fees for residents of long-term-care homes versus all other recipients, by age category. In 2015/16, the group of patients with the highest amount of dispensing fees paid was long-term-care residents in the 65–69 year age bracket, at $2,195 per patient.

Frequency of dispensing, and therefore higher total dispensing fees, for long-term-care home

Figure 14: Comparison of Dispensing Fees for Pharmacies Serving Residents of Long-Term-Care Homes vs. All Other Recipients, by Age Group, 2015/16

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

	Dispensing Fee per Recipient ($)	
Age	Long-Term Care Home	Other
0–64	2,011	409
65–69	2,195	220
70–79	2,033	280
80–89	1,882	433
90–100	1,689	599
100+	1,291	580

recipients are expected to be comparatively high because these recipients are generally older and sicker, and they change drugs more often than seniors not living in long-term-care homes. Often these recipients try a combination of drugs for a short time to assess the medication's effectiveness, and may alter dosages and/or drugs until they find the right medication plan.

Despite this, we found that other provinces pay pharmacies significantly less in dispensing fees for claims relating to residents of long-term-care homes. In British Columbia, pharmacies receive a monthly capitation fee (that is, a per person flat fee) of $43.75 for each occupied bed in a long-term-care home. If Ontario adopted this model, total dispensing fees paid to pharmacies serving long-term-care homes would be about $41 million ($43.75 x 12 months x 78,000 occupied long-term-care home beds), about $149 million less than what was actually paid in 2015/16. See **Figure 15** for a comparison of dispensing fees for long-term-care homes across provinces that have separate dispensing fee policies for residents of these homes. Manitoba has also adopted a capitation funding model for residents of long-term-care homes, where pharmacies receive between $47.80 and $48.70 per month for each occupied bed. Using this range, Ontario would pay between about $144 million and $145 million less than what was actually paid in 2015/16.

Ministry Does Not Limit Dispensing Fees for Pharmacies Serving Long-Term-Care Homes

Except in certain circumstances, the Ministry will pay a maximum of only two dispensing fees for a listed drug product in a 28-day period. As of October 1, 2015, for chronic-use drugs, the Ministry has not paid more than five dispensing fees in a year. However, these limitations do not apply to eligible recipients who reside in long-term-care homes. As a result, if pharmacies choose to supply drugs on a weekly basis they can charge four dispensing fees for each listed drug product per month. In 2015/16, the frequency of dispensing fees per drug per patient in long-term-care homes was approximately weekly, or equivalent to 52 times a year.

In 2015/16, there were approximately 50 pharmacies whose dispensing fees for residents of long-term-care homes were greater than the average of $1,820 per recipient. Of these, 15 were greater than $2,500 per recipient, five were almost $3,000 per recipient, and one was $3,200 per recipient. The Ministry has not looked into reasons why these pharmacies were dispensing higher than average amounts.

We noted that on October 1, 2015, the Ministry decreased the Ontario Drug Benefit dispensing fee paid to pharmacies for claims of residents of long-term-care homes by $1.26 (from $8.83 to $7.57). However, the Ministry did not consider whether the frequency of dispensing was reasonable and/or whether the existing funding model

Figure 15: Provincial Comparison of Dispensing Fees for Pharmacies Serving Residents of Long-Term-Care Homes
Prepared by the Office of the Auditor General of Ontario

	Dispensing Fee Amount	
Province	**Fee per Bed Served (Capitation)**	**Fee per Dispense**
Ontario	–	Between $7.57 and $11.99 per drug, depending on geographical location of pharmacy
British Columbia	$43.75 per month for each occupied bed	–
Manitoba	Between $47.80 and $48.70 per month for each occupied bed, depending on geographical area	–
Prince Edward Island	$76.52 per month for each occupied bed	–

Note: Provinces and territories not listed do not have specific policies for long-term-care home recipients.

encourages over-dispensing to recipients in long-term-care homes.

Dispensing fees cover services such as general operating costs (such as salaries and rent), stocking medication, maintaining medical records and sharing them with physicians, and discussing the patient's treatment.

RECOMMENDATION 9

To help ensure that the dispensing fees paid for recipients at long-term-care homes are reasonable, we recommend that the Ministry of Health and Long-Term Care conduct further analysis to determine the reasons for high dispensing fees for residents in certain homes and decide whether a change of dispensing policy, such as implementing limitations on frequency of dispensing fees, is required.

MINISTRY RESPONSE

The Ministry supports further analyses of dispensing fees for long-term-care homes. Effective October 1, 2015, the Ministry reduced the dispensing fees for claims paid for long-term-care home residents by $1.26 (from $8.83 to $7.57), resulting in a saving of almost $30 million annually. The Ministry will explore opportunities to improve efficiencies and value, including assessing the relationships between long-term-care homes and pharmacies.

4.8 Opioid-Related Overdoses and Deaths Continue to Rise

4.8.1 Pressing Issues Related to Use of Opioids

Opioids are potent narcotics used to treat pain. Prescribed appropriately, opioids are effective in relieving severe pain; however, their use can also result in significant harm such as addiction, overdoses and increased risk of death. Recent increases in death and overdose rates resulting from opioid use have caused Canadians and their governments to recognize that Ontario and other regions in Canada are experiencing an opioid crisis.

Despite the Ministry's efforts, described in **Section 4.8.2**, to address the opioid crisis, opioid-related overdoses and deaths are on the rise. Public Health Ontario reported the following trends:

- Emergency department visits due to opioid-related adverse events increased by 112% between 2005 and 2016, from 2,086 to 4,427 visits.
- Opioid-related deaths increased by 95% between 2005 and 2016, from 444 deaths to 865 deaths.

In May 2017, Health Quality Ontario, the provincial adviser on quality of health care, reported that the opioids being prescribed have shifted toward stronger types like hydromorphone and away from weaker opioids like codeine.

The report also noted that nearly two million people in Ontario, or about one in seven Ontarians, fill prescriptions for opioids every year. About 531,000 of these two million people are 65 and older, meaning that the Ontario Drug Benefit Program covers the drugs they are prescribed. (The Ontario Drug Benefit Program amounts to 92% of all Ontario Public Drug Programs' expenditures.) These seniors make up the majority of the approximately 720,000 patients whose opioid prescriptions the Ontario Drug Benefit Program covered in 2016/17.

The Ministry spent $157 million through the Ontario Drug Benefit Program on opioids for these 720,000 patients in 2016/17. This represents a slight increase of 6% in total expenditures and 8% in total number of patients since 2008/09. However, the number of prescriptions for opioids covered by the Ontario Drug Benefit Program increased by 62%, from 3.75 million in 2008/09 to 6.08 million in 2016/17, and the total quantity of opioids dispensed increased by 15% over the same period. We noted that more patients are now being prescribed opioids at more frequent intervals with smaller dosage per prescription, and also that the overall quantity of prescribed opioids covered

through the Ontario Drug Benefit Program has increased at a faster pace since 2008/09 than the number of patients receiving them. In addition, the total oral morphine equivalents dispensed for total high- and low-strength opioids continues to decline.

4.8.2 Ministry's Initiatives to Address Inappropriate and Unsafe Use of Opioids

Governments have the ability to potentially make a difference in areas such as controlling the availability of opioids; influencing how physicians and pharmacists prescribe and dispense the drugs; setting up harm-reduction strategies for opioid users; co-operating with other stakeholders to discover the source of drugs responsible for overdoses and deaths (prescribed drugs or street drugs); and working with stakeholders and others to understand the scope of the problem, in order to take further evidence-based measures. The Ministry has taken a number of actions to help address the growing concern over inappropriate opioid use and its health consequences, but the results are still unclear as overdoses and deaths continue to rise.

Detection and Preventive Measures

In April 2012, the Ministry implemented the Narcotics Monitoring System to collect dispensing data from all Ontario pharmacies for all narcotics and controlled substances, including drugs paid for by private insurance companies and by patients out-of-pocket. Data collected includes the name and strength of the drug, the patient who received the drug, the physician who prescribed the drug, and the quantity of drug dispensed.

In 2013, the Ministry established the Narcotics Monitoring Working Group, including representatives from the College of Physicians and Surgeons of Ontario, Ontario Medical Association, Ontario College of Pharmacists and Ontario Pharmacists Association. This working group reviewed and analyzed dispensing data from the Narcotics Monitoring System to understand prescribing and dispensing patterns of narcotics across the province. The working group also flagged some physicians and pharmacies with potential problematic prescribing and dispensing patterns to refer to their corresponding regulatory bodies for investigation.

In spring 2017, the Prescription Monitoring Leadership Roundtable was established with broader membership to play a leadership role in the identification and management of potentially high-risk use of narcotics and other monitored drugs in order to ensure patient safety.

Effective January 2017, several high-strength formulations of long-acting opioids were delisted from the Formulary as a way to encourage appropriate prescribing, and to limit opportunities for the inappropriate use and abuse of these drugs.

In April 2017, emergency rooms began reporting cases of opioid overdoses on a weekly basis to the Ministry. While the Ministry already collects this information on a quarterly basis, this new initiative ensures more timely data submissions and dissemination of reports. Data includes information on patient age and gender, whether the overdose was accidental or intentional, the number of patients who were dead on arrival, and the percentage of patients arriving by ambulance.

Life-Saving Measures

In August 2017, the Province announced $222 million in new investments over three years to enhance Ontario's Strategy to Prevent Opioid Addiction and Overdose. Among other things, the new investments are to include expanding the supply of an overdose-reversal drug (called naloxone) through emergency departments and expanding harm-reduction services, such as needle exchange programs and supervised injection sites.

Addiction Medicine Clinics for Opioid-Dependent Patients

The Ministry plans to expand the Rapid Access Addiction Medicine Clinics across the Province, which provide people with immediate and ongoing addiction treatment, counselling and other

mental health supports, and increasing access to community-based withdrawal management services and addictions programs. The Ministry is also working with the Centre for Addiction and Mental Health to expand addictions treatment and care provided in family health teams across the province.

4.8.3 More Information Is Needed for Better Decision-Making

Although the number of opioid-related overdoses and deaths is on the rise, the Ministry does not know the reasons for these overdoses and deaths, and also does not know whether the patients obtained the opioids from a pharmacist, with a legitimate prescription or not, or illegally on the street. The opioid overdoses and deaths reported by Ontario hospitals and/or the Office of the Chief Coroner for Ontario have not been linked to the Ministry's Narcotics Monitoring System to identify whether the patients had previously been prescribed or dispensed legal opioids or if they had taken illicit opioids. Having this knowledge would let the Ministry, and other areas of government such as law enforcement on drug trafficking, know where to devote resources.

Much of this uncertainty exists because the root problems behind the opioid crisis are many and complicated. Many variables such as social, environmental and psychological issues can contribute to inappropriate drug use. There is no single effective solution to help all people who are addicted to opioids or who might become addicted to the drugs they are prescribed to treat their medical conditions.

The use of opioids may start with prescriptions by physicians who are trying to help their patients to relieve pain. In some cases, patients become addicted; once a person is heavily dependent on opioids, it is very difficult to stop using them. Some physicians and other stakeholders have noted their concern that some of the patients who start to buy illegal opioids may have been on prescription opioids for some time and their physician has begun to reduce the dosage according to the recent Canadian Guideline for Opioids for Chronic Non-Cancer Pain. This unintended result—leading patients to seek out illegal drugs to treat their symptoms—further points out the limited effectiveness of the proposed solutions to this complex problem. When such patients are not able to handle their withdrawal symptoms and are not covered by any public or private drug plans, they may seek cheaper illegal drugs, such as heroin and fentanyl, on the street.

RECOMMENDATION 10

To help reduce the risk of inappropriate prescribing, dispensing and patient use of opioids, we recommend that the Ministry of Health and Long-Term Care:

- work with Ontario hospitals and the Office of the Chief Coroner for Ontario to link reported overdoses and deaths to the Ministry's Narcotics Monitoring System in order to identify whether those patients who suffered from overdoses or died obtained their opioids from legal or illicit sources; and
- consolidate, monitor and analyze data from its key initiatives to determine whether they are successful in reducing the number of individuals suffering from opioid addiction and overdoses, and the number of opioid-related deaths, and report publicly on how the initiatives are achieving their intended purposes.

MINISTRY RESPONSE

The Ministry supports safe and effective use of medicines to optimize health outcomes for patients. The opioid crisis in Ontario has highlighted the significance and need of the various parts of the health-care system to work together to address this critical issue and continue to implement Ontario's Strategy to Prevent Opioid Addiction and Overdose (Opioid Strategy). Recognizing the number of health-care providers

and institutions that can be involved, much has already been achieved.

The Narcotics Monitoring System (NMS) captures only those opioid prescription claims prescribed by an authorized prescriber, and subsequently dispensed by an authorized pharmacy. Illicit purchases and supplies of opioids obtained by Ontarians are not captured within the NMS. The Ministry is working with our partners to gather information and analyze the impact of both prescription and illicit opioid drug use in opioid-related overdoses and deaths. Linkage between the NMS and both emergency department visits for opioid overdose and coroner's data on opioid-related deaths is anticipated for 2018. The Ministry is exploring how this information and other opioid-related data can be best shared with the public in a meaningful manner.

The recommendations further emphasize that the Opioid Strategy is a multi-pronged approach involving many areas of the Ministry. The Ministry will continue to work with government partners to support the effective implementation of the Opioid Strategy, and continue to support ongoing and continuous evaluative efforts to determine the effectiveness and outcomes of the Opioid Strategy.

Appendix 1: Description of Drug Programs* in Selected Canadian Provinces

Prepared by the Office of the Auditor General of Ontario

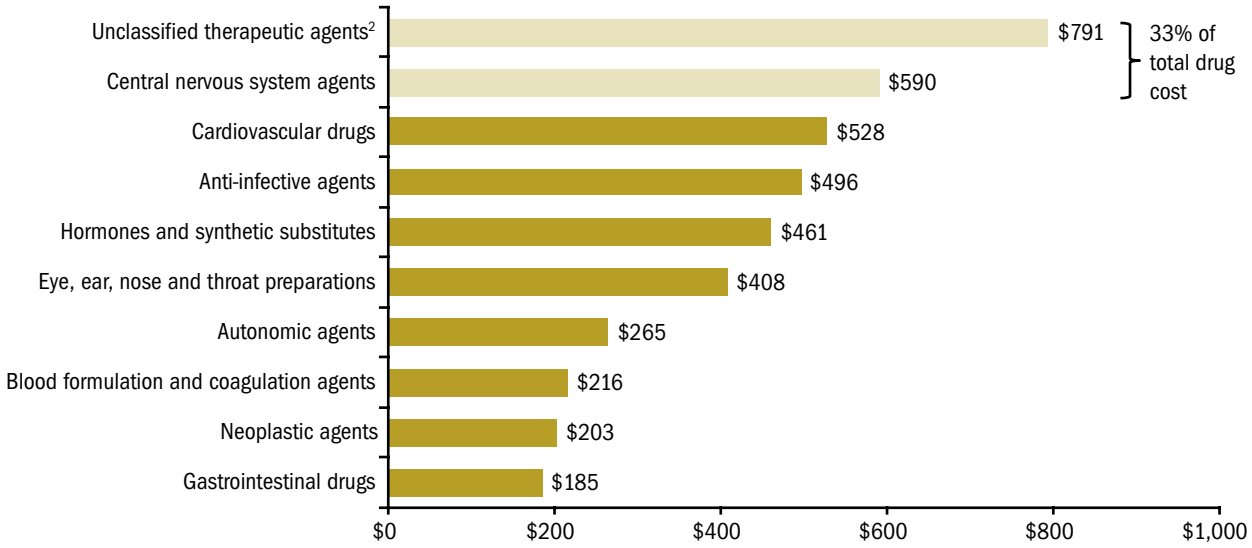
	Ontario	British Columbia	Alberta	Saskatchewan	Manitoba
Publicly funded drug program: income-based	**Trillium Drug Program** Residents who have high drug costs in relation to their household income; any residents who do not qualify under any of the other public drug plans or if their private insurance does not cover 100% of their prescription drug costs and they are not eligible for Ontario Drug Benefit coverage. **Ontario Drug Benefit Program** Recipients of Ontario Disability Support Program and Ontario Works.	**Fair PharmaCare** Universal Drug Plan—All residents are provided coverage for eligible prescription drugs and designated medical supplies, based on their net income. **Recipients of Income Assistance** Residents who are recipients of B.C. income assistance and medical benefits.	**Alberta Human Services Drug Benefit Programs with Supplement** Residents who are recipients of Alberta Human Services (e.g., Income Support, Adult Health Benefit, Assured Income for the Severely Handicapped, Child Health Benefit, Child Intervention Services, Family Support for Children with Disabilities) based on their income and needs. Coverage is provided through the specific program the recipient is enrolled in.	**Special Support Program** Residents whose drug costs are high in relation to their income. **Family Health Benefits** Low-income families with at least one child younger than 18. Eligibility is established through the Ministry of Social Services, in co-operation with Revenue Canada, based on the family income for the previous year and the number of children in the family. **Emergency Assistance** Residents who require immediate treatment with covered prescription drugs and are unable to cover their share of the cost may access one-time emergency assistance. The level of assistance provided is in accordance with ability to pay. The recipient is then required to submit a completed Special Support Application to the Drug Plan in order to receive future assistance. **Supplementary Health Benefits** Residents enrolled in a provincial income support program and residents of special care facilities eligible for the Seniors Income Plan. Per eligibility criteria, the recipient is enrolled in one of the four coverage plans available.	**Pharmacare** Eligible Manitobans whose income is seriously affected by high prescription drug costs. Coverage is based on both total family income and the amount paid for eligible prescription drugs. **Employment and Income Assistance Program** Residents who cannot support themselves or their family and are receiving financial aid from the Employment and Income Assistance Program may be eligible for drug benefits pursuant to the program.

	Ontario	British Columbia	Alberta	Saskatchewan	Manitoba
Publicly funded drug program: age-based or resident of a care setting	**Ontario Drug Benefit Program** Senior residents aged 65 or older, residents of long-term care homes and Homes for Special Care, and recipients of professional home services.	**Permanent Residents of Licensed Residential Care Facilities** Permanent residents of a licensed residential care facility receive coverage for the full cost of eligible prescription drugs.	**Seniors** Senior residents aged 65 or older and eligible dependents. Coverage includes cost of drugs minus a co-payment of 30%, up to a maximum of $25.	**Income supplement** Senior residents 65 and older qualifying for the Guaranteed Income Supplements and the Seniors Income Plan. Coverage consists of a reduced deductible on prescription drugs. **Seniors' Drug Plan** Senior residents aged 65 or older who have applied and qualified based on income. The plan covers drug costs greater than $25 per prescription.	**Personal Care Home/ Nursing Homes** Residents of personal care homes.
Publicly funded drug program: other			**Non-group plan** Optional subsidized program for residents younger than 65 and eligible dependents. Beneficiaries pay a monthly premium to receive coverage of eligible drug cost minus a co-payment of 30% up to a maximum of $25 per prescription drug.	**Children's Drug Program** Children under the age of 14. The plan covers drug costs greater than $25 per prescription.	
Residents not covered under a publicly funded drug program	• Residents younger than 65 who do not qualify for the Ontario Drug Benefit Program.		Residents younger than 65 who do not qualify for the Alberta Human Services Drug Benefit Programs with Supplement and who do not choose to opt into the Non-group plan.	• Senior residents aged 65 and older who do not qualify for Income Supplement or Seniors' Drug Plan. • Residents younger than 65 who do not qualify for the Family Health Benefits or Special Support Program.	Residents, including seniors aged 65 and older, who do not qualify for Pharmacare and for the Employment and Income Assistance Program, and who do not reside in a personal care home.

* Excludes other drug programs related to specific diseases and health conditions.

Appendix 2: Top 10 Therapeutic Drug Classes by Drug Cost,[1] 2015/16 ($ million)

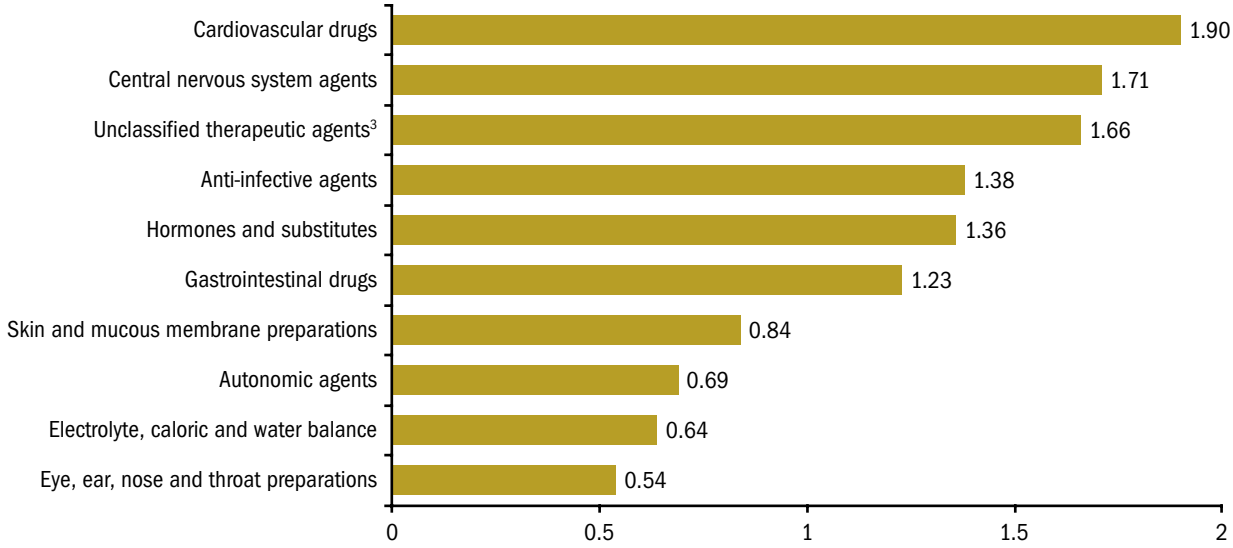
Source of data: Ministry of Health and Long-Term Care



1. Does not include New Drug Funding Program expenditures administered on behalf of the Ministry of Health and Long-Term Care (Ministry) by Cancer Care Ontario. Drug costs are based on the publicly available list prices and do not reflect the net prices paid by the Ministry under the product listing agreements with manufacturers.
2. An unclassified therapeutic agent is any drug that does not fit into any other category in the classification system. Some top drugs in this category include drugs used to treat osteoporosis, Parkinson's disease, plaque psoriasis, rheumatoid arthritis, Pompe disease, multiple sclerosis, Crohn's disease and multiple myeloma. This unclassified category is used in the American Hospital Formulary System, a classification system used internationally as well as by Health Canada.

Appendix 3: Top 10 Therapeutic Drug Classes[1] by Number of Users, 2015/16[2] (million users)

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



1. Based on the classification system of the American Hospital Formulary Service of the American Society of Health-System Pharmacists (AHFS-ASHP).
2. Total number of users 2015/16: 3 million.
3. An unclassified therapeutic agent is any drug that does not fit into any other category in the classification system. Some top drugs in this category include drugs used to treat osteoporosis, Parkinson's disease, plaque psoriasis, rheumatoid arthritis, Pompe disease, multiple sclerosis, Crohn's disease and multiple myeloma.

Appendix 4: Top 10 Drugs by Drug Cost,[1] 2015/16 ($ million)

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

Rank	Drug Name	Class	Drug Cost ($ million)	% Total Drug Cost
1	Ranibizumab (Lucentis)	Eye, ear, nose and throat	278	**6.3**
2	Ledipasvir and sofosbuvir (Harvoni)	Anti-infective agents	202	**4.6**
3	Diagnostic agent—diabetes	Diagnostic agents	108	**2.5**
4	Infliximab (Remicade)	Unclassified[2]	104	**2.4**
5	Salmeterol xinafoate and fluticasone propionate (Advair)	Autonomic agents	85	**1.9**
6	Duloxetine (Cymbalta)	Central nervous system	77	**1.7**
7	Lenalidomide (Revlimid)	Unclassified[3]	73	**1.7**
8	Sitagliptin phosphate monohydrate (Januvia)	Hormones and substitutes	72	**1.6**
9	Insulin glargine (Lantus)	Hormones and substitutes	67	**1.5**
10	Metformin and sitagliptin (Janumet)	Hormones and substitutes	66	**1.5**
Total			**1,132**	**25.7**

1. Drug cost is based on the publicly available list price and does not reflect the net price paid by the Ministry of Health and Long-Term Care under the product listing agreements with manufacturers.
2. This drug is primarily funded for rheumatology and inflammatory bowel disease.
3. This drug is primarily funded for myelodysplastic syndromes.

Appendix 5: Comparison of Medication Review Programs across Canada*

Prepared by the Office of the Auditor General of Ontario

	Ontario	British Columbia	Alberta	Saskatchewan	Nova Scotia	New Brunswick	Prince Edward Island	Newfoundland and Labrador
Initial Review	**MedsCheck Annual** • $60 per patient • Publicly funded for all residents who meet the eligibility criteria (with over 3 prescribed medications) • Maximum 1 annually **MedsCheck for Diabetes Annual** • $75 per patient • Publicly funded for all residents with diabetes • Maximum 1 annually **MedsCheck at Home** • $150 per patient • Publicly funded for all residents who are unable to attend the pharmacy in person and taking more than three prescribed medications for a chronic condition • Maximum 1 annually **MedsCheck for Long-Term Care** • $90 per patient • Publicly funded for all residents who are in long-term care homes • Maximum 1 annually	**Medication Review – Standard** • $60 per patient • Publicly funded for all residents who meet the eligibility criteria (with over 5 prescribed medications) • Maximum 2 annually, 6 months apart **Annual Medication Review – Pharmacist Consultation** • $70 per patient • Undertaken only when a medication management issue has been identified by a pharmacist during a standard Medication Review	**Comprehensive Annual Care Plan (ACCP)** • $100 or $125 for a pharmacist with additional prescribing authority (APA) • Publicly funded for all residents who meet the eligibility criteria (with at least two chronic health conditions or one chronic health condition and other risk factors) • Maximum 1 annually **Standard Medication Management Assessment** • $60 or $75 for a pharmacist with APA • Publicly funded for residents who do not meet the eligibility criteria for ACCP but have at least one chronic health condition and are taking three or more medications • Maximum 1 annually	**Medication Assessment** • $60 per patient • Publicly funded to Seniors (65+) who are beneficiaries of a provincial drug plan only • Maximum 1 annually	**Basic Medication Review** • $52.50 per patient • Publicly funded for beneficiaries of a provincial drug plan only. All other patients may receive this service for a fee • Maximum 1 annually **Advance Medication Review** • $150 per patient • Publicly funded for seniors (65+) who are beneficiaries of a provincial drug plan. All other seniors may receive this service for a fee • Maximum 1 annually	**PharmaCheck** • $52.50 per patient • Publicly funded for low-income seniors (65+) and other low-income beneficiaries of a provincial drug plan only • Maximum 1 annually	**Medication Review** • $52.50 per patient • Publicly funded for beneficiaries of provincial drug plan only • Maximum 1 annually **Diabetic Medication Review** • $65 • Publicly funded for diabetic residents • Maximum 1 annually	**Medication Review** • $52.50 per patient • Publicly funded for beneficiaries of provincial drug plan only • Maximum 1 annually **Medication Review for Chronic Obstructive Pulmonary Disease** • $52.50 per patient • Publicly funded for senior (65+) beneficiaries of provincial drug plan

	Ontario	British Columbia	Alberta	Saskatchewan	Nova Scotia	New Brunswick	Prince Edward Island	Newfoundland and Labrador
Follow-up Review	**MedsCheck Follow-up (Annual and Diabetes)** • $25 • No maximum (available upon change in patient medication profile, or as scheduled by a pharmacist) **MedsCheck for Long-Term Care Follow-up** • $50 • Maximum 4 annually	**Medication Review Follow-up** • $15 per patient • Maximum 4 annually	**Follow-up:** • $20 or $25 for pharmacists with APA • No maximum (available upon change in patient medication profile, or as scheduled by a pharmacist)	**Medication Assessment Follow-up** • $20 per patient • Maximum 2 annually	**Medication Review Follow-up:** • $20 per patient • Maximum 2 annually	Not applicable	**Medication Review Follow-up:** • $20 per patient • Maximum 4 annually **Diabetic Medication Review Follow-up:** • $25 per patient • Maximum 4 annually	Not applicable

* Only includes provinces where comparable, publicly funded medication review programs exist.

Appendix 6: Audit Criteria

Prepared by the Office of the Auditor General of Ontario

1.	Listing and/or funding decisions on drugs are evidence-based, cost-effective, and made in a timely manner.
2.	Negotiations with drug manufacturers are conducted to achieve the best price possible for publicly funded drugs.
3.	Eligibility is assessed in a timely, accurate and consistent manner to ensure coverage of drugs and pharmacy services are provided to eligible recipients.
4.	Claims for drugs and pharmacy services submitted by pharmacies and other dispensers are for eligible recipients and paid in accordance with relevant legislation, policies and agreements. Effective monitoring and enforcement mechanisms are in place to ensure payments to pharmacies and other dispensers are appropriate.
5.	Drug dispensing patterns are analyzed and used to improve patient care and medication use.
6.	Timely, accurate and complete data on the effectiveness of the Ministry of Health and Long-Term Care's (Ministry's) drug programs, including payments for pharmacy services, is collected, analyzed and used for decision-making and program improvements. Key performance measures relevant to the drug programs are reported publicly to Ontarians.
7.	The Ministry reviews and assesses the overall drug funding and procurement processes on a timely basis within the health sector, including hospitals, to identify opportunities for additional cost savings.

Appendix 7: Drug Approval and Funding Process for Brand-Name Drugs in Canada and Ontario, Effective April 1, 2016

Prepared by the Office of the Auditor General of Ontario

Drug Review for Sale in Canada

- Drug manufacturer submits scientific evidence of the product's safety, efficacy and quality to be reviewed by Health Canada,[1] which decides whether to approve the drug for sale in Canada.

Health Technology Assessment

National		Ontario
Non-cancer Drugs	**Cancer Drugs**	**Drugs Previously Reviewed, or Not Eligible for Review, by the Common Drug Review or the pan-Canadian Oncology Drug Review**
• Drug manufacturers submit clinical and economic evidence to justify public funding to be reviewed by the expert advisory committee to the Common Drug Review,[2] which decides whether to recommend that federal/provincial/territorial drug plans fund the drug for the indications requested.	• Drug manufacturers submit clinical and economic evidence to justify public funding to be reviewed by the expert review committee of the pan-Canadian Oncology Drug Review,[2] which decides whether to recommend that federal/provincial/territorial drug plans fund the drug for the indications requested.	• On a case-by-case basis, the Ministry of Health and Long-Term Care (Ministry) may seek additional advice from the Committee to Evaluate Drugs[3] on a drug that was previously reviewed by the Common Drug Review or pan-Canadian Oncology Drug Review. • The Committee to Evaluate Drugs also reviews Ontario-specific drug funding requests that are not eligible for the national process under the Common Drug Review or pan-Canadian Oncology Drug Review, such as line extensions of already marketed drugs. • The Committee to Evaluate Drugs conducts assessments of the drugs based on scientific evidence, clinical data, patient input and cost-effectiveness compared to existing funded treatments in Ontario, and recommends to the Ministry whether or not the drugs should be listed on the Ministry's Formulary, funded through the Exceptional Access Program on a case-by-case basis, or not funded at all.

Negotiation

- Based on the final recommendation issued by the Common Drug Review and pan-Canadian Oncology Drug Review and/or Ontario's Committee to Evaluate Drugs, the Ministry may enter into negotiations with the manufacturer through the pan-Canadian Pharmaceutical Alliance collectively with other jurisdictions, or individually if it is an Ontario-specific drug funding consideration. The outcome of the negotiations will help inform the final funding decision.

Final Decision

The Ministry's Executive Officer of the Ontario Public Drug Programs makes final drug funding decisions based on various factors such as:

- recommendations and advice from various committees and advisory bodies;
- patient and societal impact, and public interest; and
- budgets for the drug programs and the outcomes of negotiations for product listing agreements with manufacturers.

1. Health Canada is a federal agency that reviews and authorizes a drug before it can be marketed in Canada. It bases its authorization on scientific evidence concerning a drug's safety and efficacy in one or more specific indications (e.g., in the treatment of one or more particular diseases) as well as the quality of the drug product. Health Canada does not consider drug prices or comparative cost-effectiveness when granting market authorization. If Health Canada approves a drug, it issues the drug a Drug Identification Number.
2. Drug manufacturers must also file a submission to either the Common Drug Review (for non-cancer drugs) or the pan-Canadian Oncology Drug Review (for cancer drugs) to justify public funding for the drug based on clinical and economic evidence. Both the Common Drug Review and pan-Canadian Oncology Drug Review are administered by the Canadian Agency for Drugs and Technologies in Health, an independent, not-for-profit organization established by federal, provincial and territorial governments. It evaluates submissions from drug manufacturers and makes evidence-based reimbursement recommendations to Canada's federal, provincial and territorial public drug plans (with the exception of Quebec).
3. The Committee to Evaluate Drugs is the Ministry's own expert committee that provides advice to the Executive Officer of the Ontario Public Drug Programs on whether or not a drug should be listed on the Ontario Drug Benefit Formulary or funded through the Exceptional Access Program on a case-by-case basis. The Committee conducts assessments based on scientific evidence, clinical data, patient input and cost-effectiveness compared to existing funded treatments in Ontario.

Appendix 8: Comparison of Dispensing Fees among Selected Canadian Provinces and Territories as of March 31, 2017

Prepared by the Office of the Auditor General of Ontario

Jurisdiction	Maximum Dispensing Fee
Ontario	$8.83, $9.93, $12.14 or $13.25 depending on geographic location
British Columbia	$10.00
Alberta	$12.30
Saskatchewan	$11.40
Manitoba	The professional fee for Pharmacare is equal to the amount regularly charged by a pharmacist to persons who are responsible for paying the fee without reimbursement. The Employment and Income Assistance Program has a maximum professional fee of $6.95.
New Brunswick	$11.00*
Nova Scotia	$11.65
Prince Edward Island	$12.36
Newfoundland and Labrador	The professional fees for the Foundation Plan, Access Plan and Assurance Plan are: • $11.96 for drug costs between $0 and $49.99 • $23.93 for drug costs between $50 and $249.99 • $50 for drug costs of $250+ The professional fees for the 65Plus Plan are: • $12 for drug costs between $0 and $249.99 • $40 for drug costs of $250+
Yukon Territory	$8.75

* The dispensing fee is $9.50 for drugs for opioid dependence.