Alberta Pharmaceutical STRATEGY





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introduction

Among the key priorities of the *Health Action Plan* is the need to take action to develop sound provincial policy on matters related to the funding and utilization of prescription drugs and the management of drug benefit programs.

1.1 Purpose: An Accessible, Sustainable and Affordable Pharmaceutical System for Alberta

Albertans place great value on their health system and appreciate the many essential services and benefits that it provides. At the same time, they are concerned about the future sustainability of that system in the face of access problems and the steadily rising costs of health-related goods and services. In April 2008, the Alberta government took up the challenge of addressing these and other issues and announced the launch of a *Health Action Plan*. The plan puts Alberta on track for a more efficient, effective, responsive and sustainable health system.

Among the key priorities of the *Health Action Plan* is the need to take action to develop sound provincial policy on matters related to the funding and utilization of prescription drugs and the management of drug benefit programs. The cost of prescription drugs is rising at a much higher rate than other components of the health system and is seen as a challenge to the long-term sustainability of that system.

Prescription drugs play an increasingly important role in modern medicine. On the positive side, the appropriate use of prescription drugs can prevent or delay the onset of serious illness. However, excessive or inappropriate use of prescription drugs can be harmful. Effective drug therapies allow many people with chronic or disabling conditions to lead normal, productive lives and avoid the need for hospitalization or long-term care.

The purpose of the Alberta Pharmaceutical Strategy is to make drug coverage more accessible, affordable, efficient and therapeutically effective by improving the management, funding and purchasing processes for prescription drugs paid for fully or partially by the Government of Alberta. These processes take place in a complex commercial environment with multiple payers, customers, business interests and advocacy groups. The Alberta Pharmaceutical Strategy will bring greater clarity and consistency to the operation of government sponsored drug benefit programs and improve the efficiency and effectiveness of program governance and management.

1.2 Alberta Government Sponsored Drug Programs

The Government of Alberta supports a variety of prescription drug programs. Each program deals with the needs of a particular group of Albertans and is operated by a different government ministry. The five Government of Alberta ministries that offer drug benefit programs include:

- Health and Wellness (hospital patients, cancer patients, individuals
 with diseases such as HIV, cystic fibrosis and primary pulmonary
 hypertension, transplant patients, seniors and other Albertans in
 the community),
- Children and Youth Services (special needs children)
- Employment and Immigration (income support, child and adult health benefits),
- Seniors and Community Supports (Assured Income for the Severely Handicapped or AISH),
- Solicitor General and Public Security (people in correctional facilities).

Although each of these programs funds the drugs listed on the core drug benefit list provided by Alberta Health and Wellness, they operate with different administrative rules and eligibility criteria.

Alberta government sponsored drug programs provide benefits to approximately 20 per cent of Albertans and their clients account for approximately 45 per cent of the prescriptions filled in this province. The majority of working Albertans and their families (55 per cent) are not covered by government sponsored programs. Most of them are provided with drug benefit coverage through programs offered by and cost shared with their employers. The remaining 25 per cent of Albertans do not have any form of drug coverage; however, many of these Albertans may be young and healthy and may have opted not to seek drug benefit coverage.

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Spending on drugs is increasing at a rate three times higher than that of physician or hospital services.

1.3 Rising Costs and Sustainability Concerns

The rapidly rising cost of prescription drugs is a matter of serious concern to all Canadian provinces and to both developed and developing countries around the world. Prescription drugs represent the fastest growing cost component of Alberta's health system. Total public and private spending on prescription drugs has recently surpassed the total amount spent on physician compensation. Spending on drugs is increasing at a rate three times higher than that of physician or hospital services.

In 2006/2007, Alberta government spending on drugs totalled \$1.2 billion. Of this amount, approximately 39 per cent was paid for drugs prescribed to seniors. This proportion is expected to rise in the coming years in keeping with an increased proportion of seniors in the total population. In addition to the \$1.2 billion spent by government each year, private citizens and employers — through employee benefit programs — spend at least an equivalent amount. Based on these trends, it is estimated that government spending on prescription drugs will grow steadily and reach \$2 billion by the year 2013/2014. This does not include drug costs borne by employer-based drug plans, the federal government and the Workers Compensation Board on behalf of Albertans for whom they are responsible.

1.4 Perspectives of Albertans: Recent Consultation Findings

To support the development of the Alberta Pharmaceutical Strategy, two consultations were undertaken in 2008. The first was a discussion of improvements to the drug review process. It was commissioned by the former Minister of Health and Wellness, Dave Hancock.

The second was a consultation on issues related to the pharmaceutical strategy. It was commissioned by Minister of Health and Wellness Ron Liepert. Mr. Jonathan Denis, MLA for Calgary-Egmont, was asked by the Minister to engage a wide range of stakeholders representing different interests and perspectives. The mandate for the consultation process was to provide advice to the Minister on stakeholder feedback on issues related to access, sustainability and value options for the development of a pharmaceutical strategy.

The consultation process involved a series of face-to-face meetings throughout the summer of 2008. Stakeholders included professional colleges and associations, the pharmaceutical industry, seniors' groups, patient representatives, business associations and insurance companies. Jonathan Denis' report summarizes key findings and makes ten recommendations. The report's recommendations are summarized briefly as follows:

- 1. Consolidate all Government of Alberta drug benefits
- 2. Establish a process for independent consideration
- 3. Fully disclose all cost components on the prescription receipt
- 4. Implement transparent reporting of drug coverage decisions
- 5. Enhance the drug review and listing process
- 6. Make drug coverage decisions in a timely manner
- 7. Simplify special authorization policies and process
- 8. Coordinate drug procurement and drug pricing negotiations with other jurisdictions
- 9. Establish industry relations code and conflict of interest guidelines for product promotion
- 10. Create opportunities for pharmacists to adopt a patient centric professional service model.

MLA Jonathan Denis' report summarizes key findings and makes ten recommendations.

The goal of the Alberta Pharmaceutical Strategy is to make drug coverage more accessible, affordable, efficient and therapeutically effective.

1.5 Key Components of the Alberta Pharmaceutical Strategy

The goal of the Alberta Pharmaceutical Strategy is to make drug coverage more accessible, affordable, efficient and therapeutically effective. Supported by a legislative framework, the strategy will be undertaken in two phases to achieve the following deliverables:

- Redesigned drug coverage for Alberta seniors
- Revised premiums for the non-group drug benefit program to be consistent with marketed programs
- A common program and approach to drug coverage by government
- A program to support individuals who require access to drug therapy to treat rare diseases
- A more timely and transparent drug approval process
- · An improved process for drug pricing and purchasing
- A more flexible practice and payment model to promote patient-centered pharmacy services

Recognizing that the issues and changes required to achieve these deliverables need to be addressed in a logical sequence of steps, the Alberta Pharmaceutical Strategy will be implemented in two consecutive phases. Phase one will address administrative, organizational and procedural issues associated with existing government sponsored drug programs and reflect the findings of the Jonathan Denis report. The actions planned for phase two require further analysis, consultation and discussion as well as the results of a pilot project.

2.0 PHASE ONE:

KEY COMPONENTS

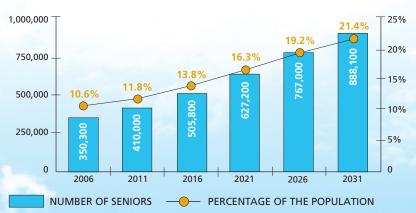


2.1 Redesigning Drug Coverage for Seniors

Regardless of their income and assets, Alberta seniors and their dependents are currently eligible for premium-free drug coverage. It is administered on behalf of the Alberta government by Alberta Blue Cross. Under this program, seniors pay 30 per cent of the cost of their prescriptions to a maximum of \$25 per prescription. There is general agreement that seniors should have a drug coverage program that supports access to appropriate and necessary therapies, but the program should also allow for fair and equitable cost sharing based on an individual's or family's ability to pay. Current data on household income of Albertans suggests that many seniors are in a position to further contribute to the cost of drug therapy without undue hardship.

On average, seniors use health services at a much higher rate than other Albertans and they also require more prescription drugs. Under the seniors drug benefit program, government currently spends approximately \$1,600 per senior family per year on prescription drugs. Today, seniors make up approximately 11 per cent of the Alberta population and this proportion will rise to 16 per cent by the year 2020 as shown in the following graph:

Number And Percentage Of Seniors In Alberta



Source: Statistics Canada, Population Projections for Canada, Provinces and Territories 2005-2031 (Scenario 3)

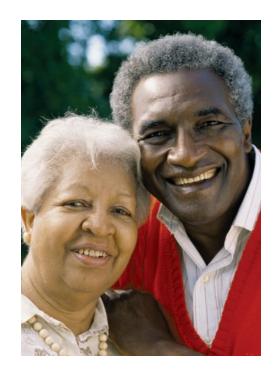
Revised December 2006

The baby boomers, who will become senior citizens over the coming decade, are expected to have higher incomes than their predecessors. At the present time in Alberta, approximately 44 per cent of single seniors have an annual income below \$21,325 and approximately 38 per cent of senior families have an annual income below \$42,650. Looking ahead, future generations of seniors are expected to have higher incomes. Although today's seniors have higher levels of education and longer life expectancies than past seniors, there are some trends that raise questions about the quality of life that future seniors will have. For instance, Alberta's population is experiencing rising rates of obesity, chronic illness and mental health problems. Sixty-one per cent of Canadian baby boomers still have a mortgage on their home.

Low-income seniors will not pay for drug coverage. About 44 per cent of single seniors (63,000 seniors) and 38 per cent of families (49,000 families) will receive free drug coverage – a co-payment of up to \$25 per prescription will no longer be required.

Single seniors with an annual income of more than \$21,325 and senior families with an annual combined income of more than \$42,650 will pay a deductible based on their total income. (line 150 of tax form) These deductibles will be introduced on January 1, 2010.

Further details are provided in a fact sheet.





Seniors will be required to pay the full cost of their prescription drugs until they reach their deductible. When annual drug costs exceed their income-based deductible, the government program will cover the full cost of therapy. Seniors with few medications may not reach their deductible, while those on many medications or medications that are very expensive may quickly exceed their deductible.

Deductible Rates for Single Seniors						
Single Senior Income (Line 150)	Single Senior Deductible (Per cent)	Deductible Range (Dollars)				
\$0 to \$21,325	0.00%	\$0				
\$21,326 to \$26,325	0.70%	\$149 to \$184				
\$26,326 to \$31,325	1.40%	\$369 to \$439				
\$31,326 to \$36,325	2.10%	\$658 to \$763				
\$36,326 to \$41,325	2.80%	\$1,017 to \$1,157				
\$41,326 to \$46,325	3.50%	\$1,446 to \$1,621				
\$46,326 to \$51,325	4.20%	\$1,946 to \$2,156				
\$51,326 to \$56,325	4.90%	\$2,515 to \$2,760				
\$56,326 to \$149,999	5.00%	\$2,816 to \$7,500				
\$150,000 to over	5.00%	\$7,500				

Deductible Rates for Senior Families						
Family Senior Income (Line 150)	Family Senior Deductible (Per cent)	Deductible Range (Dollars)				
\$0 to \$42,650	0.00%	\$0				
\$42,651 to \$47,650	0.70%	\$299 to \$334				
\$47,651 to \$52,650	1.40%	\$667 to \$737				
\$52,651 to \$57,650	2.10%	\$1,106 to \$1,211				
\$57,651 to \$62,650	2.80%	\$1,614 to \$1,754				
\$62,651 to \$67,650	3.50%	\$2,193 to \$2,368				
\$67,651 to \$72,650	4.20%	\$2,841 to \$3,051				
\$72,651 to \$77,650	4.90%	\$3,560 to \$3,805				
\$77,651 to \$149,999	5.00%	\$3,883 to \$7,500				
\$150,000 and over	5.00%	\$7,500				

2.2 Non-Group Drug Benefit

The premium rates set by government for the non-group coverage program (administered by Alberta Blue Cross) are low in comparison to the market rates charged by private and employer-based drug programs. To achieve greater fairness and a level playing field, the premium rates charged by government for non-group coverage need to be brought closer in line with the market rates charged by private and employer-based programs. Coverage will continue to be available to all Albertans including those with pre-existing medical conditions.

Non-group coverage premiums will increase so these rates are comparable to those of employer and private plans. These premiums have not increased since 1993. This premium increase will be phased in over two years, beginning in July 2009. Further details are provided in a fact sheet.



Participants in the consultation process pointed out the confusion created by the fact that five different Alberta government ministries operate separate drug benefit programs. Inconsistencies in the drugs provided to individuals under the various provincial programs may lead to disruption of therapy as patients move from one facility to another or pass an age threshold. For example, when an individual supported by the Assured Income for the Severely Handicapped (AISH) program turns 65, they become enrolled in the seniors' drug benefit. Under the current seniors' program, they are required to start paying a co-payment of 30 per cent, to a maximum of \$25, for each prescription. Under the new aligned program, they will continue to receive their drugs at no cost. Similarly, children with cystic fibrosis who receive drugs to replace digestive enzymes under the government's program for special needs children may no longer have full coverage for these medications once they reach the age of 18 years. In addition, many Albertans are confused by the different rules and eligibility criteria used by the various private or employer-based drug benefit programs operated by Alberta Blue Cross and private insurance companies.



Current GoA Drug Programs
Seniors
Non-Seniors
Income Support Clients Child & Adult Health Benefits
Special Needs Children
AISH Recipients
People in Correctional Facilities
Hospital Patients
Cancer Patients
HIV, Transplant Patients

Planned Changes:

Seniors:

- Income-based Deductibles.
- Non deductible for individuals earning under \$21,325/year or families earning under \$42,650/year.

Non-Seniors:

- Market based premium plan for nonsenior families.
- Annual premiums and co-payments.
- Remove GoA as first payer.
- Coverage coordinated with other plans.

Social Programs:

- No Premium and No Co-Payments
- This will cover all Albertans enrolled in various GoA social programs including: AISH recipients, special needs children, income support clients, child and adult health benefits, and people in correctional facilities.

Hospital and Cancer Patients:

- Includes hospital patients, and individuals with diseases such as HIV, cystic fibrosis, primary pulmonary hypertension and transplant patients.
- No change to existing coverage.

GoA = Government of Alberta

Participants in the consultation process felt that the Government of Alberta should consolidate its various government sponsored drug benefit programs into a single "Alberta Drug Benefit Program" with clearly defined administrative processes and eligibility criteria, as well as a process for independent consideration to address the specialized needs of individual patients for whom standard treatments are neither effective nor appropriate. The independent consideration process will be separate from the Expert Committee process.

It is believed that these changes will not only contribute to the viability and sustainability of Alberta's government sponsored drug benefit programs, but they will result in greater fairness, consistency and equity across the board. The chart summarizes the changes that will be implemented.

A single, government-sponsored drug program will be established along with a common drug benefit list, resulting in a streamlined program and greater consistency and clarity on what is covered for Albertans.

2.4 Drug Coverage for Individuals with Rare Diseases

Rare diseases occur at a rate of less than one individual per 50,000 Albertans. Therapies to treat individuals with these disorders often cost more than \$250,000 per year. A program to support the funding of treatment for Albertans with these disorders is under development. As part of this strategy, an expert panel will review products and provide recommendations on coverage decisions. The panel will review individual cases to determine when to start, continue and stop therapy based on a confirmed diagnosis, expected improvements in quality of life and published criteria. There will be a residency requirement to be eligible for this program.

Further details are provided in a fact sheet.

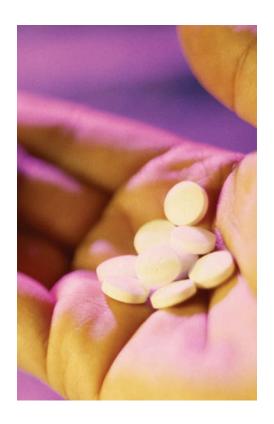
2.5 Timely and Transparent Drug Approval Process

The Expert Committee on Drug Evaluation and Therapeutics currently advises the Minister of Health and Wellness on adding drugs to the drug benefit list. The Expert Committee's recommendations are based on clinical and therapeutic value and on economic considerations. Other factors, such as value to society and social circumstances, are currently beyond the scope of the Expert Committee.

Several groups participating in the consultation sessions held by Jonathan Denis, MLA, wanted the entire process for approving drug listings to be more accountable and transparent. An important step in this direction will be to allow the consideration of societal and ethical perspectives by a public committee – in addition to the clinical and economical expertise provided by the physicians and pharmacists on the Expert Committee. It will be important to clearly define the role and expectations of public input into the drug benefit listing process. Accountability will be further enhanced by performance measures, transparency checkpoints, appeal mechanisms and processes for monitoring the patient outcomes of drug therapy.

The time required to make a drug listing decision was also a matter of concern. It was suggested that a reasonable timeline is 30 days for generic drugs. However, since the process for approving new brand name drugs takes place at the national level, through a process known as the Common Drug Review, it was felt that a maximum of 120 days after Common Drug Review approval is a reasonable target.

The consultation process confirmed the need to streamline the existing special authorization process whereby individuals are provided coverage for complex and costly drug therapies. Delays in obtaining special authorization are attributable to the administrative procedures and forms to be filled out by attending physicians. The process for obtaining special authorization will be expedited by allowing pharmacists, in addition to physicians, to complete and submit the application forms.





A new committee consisting of public members will be formed to provide societal and ethical perspectives in addition to the therapeutic and scientific views of the Expert Committee on Drug Evaluation and Therapeutics.

Drug review guidelines and target timelines will be established so timely drug coverage decisions can be made and the rationale for these decisions is clearly understood.

Independent consideration will be provided to meet the needs of patients for whom standard drug treatments are not effective.

Further details are provided in a fact sheet.

2.6 Development of a Legislative Framework

New legislation will be needed to bring about many of the changes described in the strategy. A new statute with broad regulatory powers will be developed to provide appropriate decision making powers to those responsible for administering the Alberta government drug benefit programs. These decision making powers will enable the administrators, the Expert and the Public Committees to deal effectively with the many complex issues and processes involved in operating Alberta's publicly funded drug benefit programs.

3.0 PHASE TWO:

KEY COMPONENTS



The issues to be addressed in Phase Two are complex, interrelated and require further analysis, consultation and discussion with stakeholders.

3.1 Pricing and Purchasing of Drugs

Purchasing of pharmaceuticals takes place in two markets: the institutional market (hospitals and government agencies) and the community market (chain drug stores, grocery stores, independent pharmacies). The institutional market lends itself to a bulk-purchasing process. The community market is more complex. Pharmacies purchase drugs while government pays those pharmacies for prescriptions on behalf of individuals.

Currently, Alberta Health and Wellness is working with Alberta Health Services on a procurement and supply chain management strategy. That strategy will include processes for the purchase of drugs, capital equipment and other medical supplies needed by the health care organizations that comprise the institutional market.

Average drug prices in Canada for both brand and generic products are higher than those of most developed countries. The Fraser Institute has shown that Canadians pay less for brand products than do Americans, but Canadians pay more for generic drugs. The Competition Bureau of Canada has shown that generic manufacturers pay rebates and allowances of approximately 40 per cent to pharmacies for stocking their products. Better value may be attained from manufacturers through improved coordination of purchasing practices.

Prescription drug pricing is complex and integrated with payments for pharmacy services. Alberta Health and Wellness is assessing best practices for the purchasing of drugs. A strategy is being developed and more details will be announced in spring 2009.

Alberta will continue to explore the possibility of developing common Western Canadian drug purchasing and procurement processes.



3.2 Pharmacy Professional Practice and Reimbursement Model

At the present time, community pharmacies in Alberta are paid a dispensing fee, which provides compensation for the work involved in filling prescriptions. This payment system does not recognize or reward other professional services such as counselling patients or advising other health care providers on optimum drug therapy. Pharmacists have the skills and knowledge needed by patients and health service providers. Alberta Health and Wellness has provided grant funding to the Alberta Pharmacists' Association to undertake the pharmacy practice models initiative. This pilot project will test and evaluate new practice and reimbursement models through the fall of 2009.

Alberta Health and Wellness intends to move to a different type of incentive and reimbursement model that rewards pharmacies and pharmacists for increased involvement in patient care and appropriate drug therapy.



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