

**Report of the Provincial Working Group on
the Delivery of Oncology Medications for
Private Payment in Ontario Hospitals**

July 27, 2006



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Background

Ontario patients are surviving cancer longer and living better than at any other time in history. Five-year relative survival rates for patients with the four most common cancers is increasing (20% increase for prostate, 10% increase for breast, 6% increase for colorectal. Survival for lung cancer remains low at a 2% increase). This survival improvement is the result of better screening and early diagnosis together with more effective treatments that offer the potential for a cure, but are extremely expensive. These improvements have dramatically changed the course of cancer with the disease now often treated as a chronic illness.

Cancer Drug Funding

While determining drug funding policies for cancer drugs is currently a provincial responsibility, the federal government's role is to provide regulatory approval or Notice of Compliance (NOC) to allow drugs to be marketed in Canada. In addition, the federal government operates a Special Access Program (SAP) to allow for access to drugs not currently licensed for sale in Canada.

Ontario's program for funding new intravenous (IV) cancer drugs in hospitals, the New Drug Funding Program (NDFP), is designed so that all IV drugs funded by the program are supported by clinical guidelines developed by Cancer Care Ontario's internationally recognized Program in Evidence-Based Care (PEBC). Use of these guidelines ensures drugs are delivered according to the best standards of care. This is part of an extremely positive shift in Ontario over the last decade towards using the latest scientific evidence to support the evaluation and use of new cancer drugs. This process has brought

a new level of independence and integrity to complex decisions about the merits of new drugs.

The New Drug Funding Program (NDFP) funds about 75% of the costs of all IV cancer drugs administered in hospitals. Hospitals cover the other 25%, for older drugs approved before the NDFP was created in the mid-1990s. Some IV drugs that are not funded by the NDFP or by hospitals' budgets are available for private payment and administered outside of hospitals.

Non-intravenous cancer drugs available outside of hospitals, including pills and injectable drugs, are covered in four ways. The Ontario Drug Benefit (ODB) program covers non-IV drugs for seniors and people on family benefits, and the Trillium Program assists residents with high prescription costs relative to their incomes. Many other people have private insurance or insurance offered through employment, or pay out of pocket.

Currently, the only options for patients who have been prescribed one of these unfunded IV drugs are to go to a single private clinic in Toronto or to go to the U.S. In either case, the patients pay substantially more than they would if the drug were offered in an Ontario hospital.

Unprecedented growth of drug costs

The NDFP was created to improve consistency and equity for patients requiring chemotherapy and other intravenous cancer drugs. Prior to this program, each hospital paid for its own IV cancer drugs, which created a patchwork of access at hospitals and in regions across the province. Moreover, decisions were not always based on medical and economic evidence.

The NDFP was created in 1995 to fund Paclitaxel (Taxol) for breast and ovarian cancer, the first of the new and very expensive “blockbuster” IV cancer drugs. In 1997, the program expanded to include other new IV cancer drugs. Today, the NDFP covers 19 drugs and 48 indications for existing cancer drugs. Over the last decade, the price and overall cost of these new IV cancer drugs has been growing at an unprecedented rate. In recent years, as new indications and new drugs were added, the program has been growing by approximately 35% each year. This compares to single-digit growth for the overall health care budget in the past few years. The number of new anticancer agents in development or close to launch means that spending on new cancer drugs will continue to rise significantly in the foreseeable future. Many of these new drugs are considered to be more costly to research and develop, and accordingly, manufacturers are increasing the costs to consumers.

New Approval Process for Cancer Drugs

Prior to 2005, cancer drugs were approved by a Policy Advisory Committee that assessed the merit of drugs based on the medical evidence. This process did not include an economic evaluation.

In 2005, Ontario created a more accountable evidence-based process for evaluating and approving new and expensive cancer drugs – both IV and non-IV. This was based on the understanding that in a public health care system, people not only have a responsibility to provide patients with the highest quality of care, but also a responsibility to citizens to spend health care dollars wisely and in a way that produces the greatest benefits for patients and value for society.

The review process

An independent cancer subcommittee of the province’s Drug Quality and Therapeutics Committee (DQTC) was created including physicians, health economists, pharmacists and ethicists. This committee makes decisions based on the best available evidence of medical benefit. It then factors in pharmacoeconomic evidence, which is the degree of medical benefit provided by a drug relative to its cost. The committee makes a recommendation to the full DQTC, which is also independent of government. The DQTC, in turn, makes a recommendation to the Ministry of Health and Long-Term Care.

This new process has brought a higher level of rigour to cancer drug funding decisions. In the past, pharmacoeconomic evidence was never considered and, as a result, exceptionally high-priced cancer drugs with limited medical benefits may have been treated the same as lower cost drugs with significant medical benefits. In addition, there were separate approval processes for NDFP and ODB cancer drugs. By evaluating drugs for both programs, this new process has improved the consistency and equity of funding decisions for cancer drugs.

Making difficult choices

Like all health care systems and organizations that must work within budgets, the committee makes choices by weighing the degree of medical benefit of drugs against their cost. There are various reasons why a new drug or indication does not receive funding approval. There may not be enough evidence or enough high-quality evidence of its effectiveness to support funding the drug; the drug’s medical benefit might be limited; the drug may not offer enough of a benefit over treatments

that are already available; and the potential dangers or side effects of the drug may outweigh its benefits.

The tradeoffs that must be made in the assessment of cancer services are no different from the tradeoffs that are a fact of life for health ministries and hospitals grappling with fast-rising health care costs. Cost-effectiveness evaluation helps all western jurisdictions make these decisions. Decision-makers use evidence and expert judgments to determine the thresholds beyond which the public health care system can or cannot pay.

Need for patient and citizen input

The cancer drug approval process serves most patients well, but it is clearly not without flaws. First, the process is not transparent. Patients, the public and health care professionals are kept in the dark about the reasons for decisions, leaving them confused and undermining their confidence in crucial decisions that directly affect their lives. As well, the quality of clinical evidence tends to be considerably stronger than the pharmacoeconomic analysis for new drugs.

There is also a critical need for a societal perspective on what thresholds are appropriate. The DQTC and policy makers are doing their best to answer these difficult questions, but Ontario citizens should ultimately decide. The Ontario government's recently announced drug reform strategy offers the promise of bringing patients and the public into these decisions and lifting the veil on the decision-making process.

Regardless of the thresholds that are set, some cancer drugs will not meet the test for reimbursement. While some new and costly drugs do not meet the standards for public programs, they are important to individual patients. These patients are seeking access to unfunded drugs and oncologists are prescribing them. These include some IV drugs that have medical benefit but are not cost-effective by current yardsticks.

Few options for patients

As previously mentioned, the only options for patients in Ontario who have been prescribed these drugs have been to go to a single private clinic located in Toronto or to go to the U.S. In either case, the patients pay substantially more than they would if the drug were offered in an Ontario hospital.

In terms of accessibility, one private clinic located in Toronto will have limited benefit for cancer patients across the province who do not live in close proximity or do not have the means to travel. Treatment at a private clinic also fragments the continuity of care.

In addition, some patients have been petitioning local hospitals to infuse agents that have been privately purchased. Some patients are having some unfunded drugs administered in physician offices, which also raises patient safety issues.

There needs to be a better recourse for patients who have been prescribed these drugs. Patients are seeking these drugs through hospitals where they can be cared for by their own oncologist and care team. This is beneficial to patients because they receive better continuity of care in a safe and familiar environment, closer to home.

The Provincial Working Group

A working group supported by Cancer Care Ontario – and including hospital leaders, health care professionals and health policy experts, with input from an ethicist, as well as representatives from the Ministry of Health and Long-Term Care and the Canadian Cancer Society – was created to develop advice for hospitals to respond to this situation. The group’s purpose is to ensure consistent standards and practices for providing unfunded IV cancer drugs to adult cancer patients for private payment across the province, and to ensure the highest quality and safety standards (see terms of reference in Appendix A).

The working group has been asked to make recommendations to the Ministry of Health and Long-Term Care and also to advise the Council of Academic Teaching Hospitals of Ontario (CAHO), Ontario Hospital Association (OHA), and Cancer Care Ontario (CCO).

To inform the process of the working group, there were three province-wide stakeholder engagement meetings with hospitals and cancer centres that provide IV chemotherapy to patients. This group included physicians, nurses, pharmacists and administrators.

Legal analysis undertaken by Borden Ladner Gervais LLP before the working group was struck concluded that there was no legal impediment to a hospital providing unfunded IV drugs for private payment. The group, therefore, did not address the legal dimensions of this issue, but rather, the principles of administering these drugs in a way that is best for patient care.

The working group’s recommendations apply only to new cancer drugs that have federal approval or are available through the Special Access Program for at least one indication and that have not been approved for funding in Ontario, and do not pertain in any way to drugs that are, or will be, covered by the NDFP and other public plans.

The working group members will continue to advocate and work with the government to strengthen publicly funded programs for cancer drugs and promote patients’ access to high-quality cancer drugs, including the option of creating an exceptional access program for IV drugs or a solution through the national pharmaceutical strategy on catastrophic drug coverage (i.e., expensive drugs for rare conditions). The government’s drug reform strategy and Bill 102 offer important opportunities to improve access to cancer drugs and will apply to both IV and oral drugs. In particular, conditional listing, exceptional access, partnership agreements, and patient and public input will no doubt reduce access barriers to effective new therapies.



Working Group Deliverables

In order to develop a recommended framework for Ontario hospitals to provide unfunded intravenously (IV) administered oncology medications to patients for private payment, the working group agreed upon the following key deliverables:

- 1.** Agree on common principles for formulary decision-making for IV cancer drugs that hospitals will continue to fund.
- 2.** Recommend criteria through which unfunded drugs should be provided for private payment in Ontario hospitals.
- 3.** Recommend a mechanism for prioritizing patients for treatment based on availability of resources.
- 4.** Develop the payment structure for the provision of unfunded drugs.
- 5.** Determine the optimal approach to purchasing and dispensing consistent with professional standards to ensure patient safety.
- 6.** Make recommendations concerning requirements for documentation of patient care activities.
- 7.** Develop mechanisms (e.g., review mechanisms) to ensure consistency of application across the province.



Assumptions

A number of assumptions were made to focus and direct the working group's efforts and assist them in gaining consensus on the specific deliverables without being preoccupied with the details of related issues. The following assumptions were made by the working group with respect to the final recommendations:

- According to the legal opinion prepared, the practice of hospitals providing unfunded IV drugs for private payment does not contravene the Canada Health Act or Ontario Health Insurance Act.
- The recommendations cover only the adult oncology population.
- The recommendations are not intended to result in a transfer of funding for existing services from public (i.e., hospitals and NDFP) to private (i.e., patients or insurance benefit plans) payment sources.
- CCO and hospitals will continue to advocate for a strong publicly funded cancer drug program.
 - Drug Reform Strategy and Bill 102 provide many opportunities for better access to cancer drugs (i.e., conditional listing, exceptional access, partnership agreements, patient input, etc.)
- Recommendations are intended to expand access geographically to people who have the ability to pay.
- The recommendations are made independent of the ultimate payer (e.g., patient out-of-pocket payment versus insurance benefit plan reimbursement).

Recommendations

To create the framework for the delivery of IV oncology medications for private payment in Ontario hospitals, the working group submits a number of recommendations related to each of the seven deliverables.

1. Agree on common principles for formulary decision-making for IV cancer drugs that hospitals will continue to fund

Currently in Ontario, hospital-administered intravenous (IV) cancer drugs are funded either by Cancer Care Ontario's New Drug Funding Program (NDFP) or the hospital operating budgets. The NDFP currently reimburses Ontario hospitals for the costs of 19 drugs for 48 clinical indications. This accounts for over 75% of IV cancer drug expenditures for hospitals. Hospitals' global budgets currently fund older drugs that predate the inception of the NDFP as well as drugs required for uncommon clinical circumstances where there may never be formal reimbursement through the NDFP. The goal of making recommendations with respect to developing common principles for formulary decision-making was to ensure consistency across the province of the drugs hospitals would pay for through their global budgets.

The working group recommends that the current public funding mechanism for IV cancer drugs continue, with additional clarity added to identify the types of drugs hospitals should fund outside of the NDFP. It is recommended that the hospitals continue to fund the IV oncology drugs that received Health Canada regulatory approval/Notice of Compliance (NOC) prior to 1997 (predating the establishment of the NDFP). Although two of the drugs currently included in the NDFP received

NOC prior to 1997, this date is still felt to be an appropriate cut-off since 1997 was the year that the Taxol funding program transitioned into the NDFP and all appropriate drugs at that time were moved into the NDFP. It is further recommended that the CCO on-line formulary (see link below) be used as a guide by hospitals to identify the appropriate "core" regimens containing the drugs that should be funded routinely by hospitals' global budgets.

http://www.cancercare.on.ca/index_drugFormulary.htm

The working group makes specific recommendations regarding uncommon clinical circumstances. An uncommon clinical circumstance is defined as an uncommon disease where no randomized clinical trial (RCT) evidence exists (or is likely ever to exist), or an uncommon clinical situation. It is recommended that drugs marketed before 1999 and already funded by most hospitals for a particular indication continue to be funded. The 1999 cut-off was agreed upon since this was the year that the first monoclonal antibody (Herceptin) was launched in Canada. The costs of drugs introduced into the Canadian market from 1999 onwards are much higher than the costs of products marketed prior to 1999 (i.e., \$20,000+ per patient versus an average of \$5,000 per patient). It is agreed that there must be some evidence to support the use of the drug for the indication requested and there should be a recommendation through the individual hospital's decision-making process for dealing with non-formulary drugs (e.g., multidisciplinary case conference, hospital Pharmacy and Therapeutics (P&T) committee, advice from experts within the Regional Cancer Program or LHIN) that therapy is appropriate for the patient.

2. Recommend criteria through which unfunded drugs should be provided for private payment in Ontario hospitals

A number of recommendations are made by the working group with respect to the specific circumstances under which hospitals would provide IV oncology drugs for private payment.

It is agreed that in all circumstances, before a drug is considered for private payment, it must have received regulatory approval/Notice of Compliance (NOC) from Health Canada or be available through their Special Access Program (SAP). It is further agreed that a NOC for each specific clinical indication is not necessary because many cancer drugs are currently routinely used in circumstances for which there is no NOC for the specific indication. In addition to these criteria concerning regulatory status, the following situations are considered appropriate circumstances under which hospitals would provide IV drugs for private payment to Ontario patients:

- The drug's use for the specific indication is supported by a Program in Evidence-Based Care (PEBC) practice guideline or other evidence product prepared by a CCO disease site group (DSG), and a decision has been made not to fund the drug through the NDFP.

OR

- A PEBC guideline is pending with compelling evidence and the drug may be under review, or review not initiated through the CCO-DQTC process, and there has been a recommendation through the individual hospital's decision-making

process for dealing with non-formulary drugs (e.g., multidisciplinary case conference, hospital P&T committee, advice from experts within the Regional Cancer Program or LHIN) that therapy is appropriate for the patient.

OR

- The PEBC guideline indicates there is insufficient evidence for a clear recommendation and there has been a recommendation through the individual hospital's decision-making process for dealing with non-formulary drugs (e.g., multidisciplinary case conference, hospital P&T committee, advice from experts within the Regional Cancer Program or LHIN) that therapy is appropriate for the patient.

OR

- The clinical circumstance is uncommon, and it is unlikely that the drug will be reimbursed through the NDFP for the indication, and the drug has received NOC after 1998.

The working group recommends that specific drugs not be provided by Ontario hospitals for private payment if the drug has not received regulatory approval/Notice of Compliance (NOC) from Health Canada or is not available through the Special Access Program (SAP). It is agreed that the drug not be provided by the hospitals where there is a PEBC guideline or other product prepared by a CCO DSG recommending against the use of the drug for the specific indication. Finally, the drug should not be provided for private payment if the hospital budget or the NDFP is the appropriate funding mechanism (see advice in recommendation #1).

3. Recommend a mechanism for prioritizing patients for treatment based on availability of resources

An ethical framework for decision-making was discussed with the working group prior to deciding on recommendations regarding priority setting for access to care. The working group considered the ethical issues in prioritizing patients for access to constrained public resources (i.e., nursing time, chemotherapy unit “chair time”). In balancing competing claims to these resources, it was noted that for patients accessing publicly funded, insured services and drugs, the Canada Health Act provides a right to reasonable access to these resources “without financial or other barriers.” In contrast, patients’ ability to access these resources to provide uninsured medications through private payment, while not prohibited by Ontario regulations, is not accompanied by any guarantees to access under the Canada Health Act. In assessing these competing demands, the working group determined that the primary prioritization principle that should guide the provision of IV oncology drugs for private payment was that the privately funded treatment should not displace publicly funded patients from treatment. It was further agreed and is recommended that decisions regarding prioritization of specific patients should be made according to regular practice by systemic therapy teams within hospitals, with consideration of factors such as relative urgency of care.

4. Develop the payment structure for the provision of unfunded drugs

Concerning the payment structure, the original direction provided by government was that a model be developed to provide drugs for private payment by hospitals on a “cost recovery” basis. It was further recognized by the working group that if government were to set a precedent for paying for non-drug related costs for cancer, it would be perceived as unfair not to apply this practice to other drugs/diseases in the future. It was also identified that hospitals would not be in a position to be able to treat increased patient volumes, or prepare, dispense and administer additional drugs, or counsel and monitor patients without more resources. In addition, it was anticipated that there would be increased administrative workload associated with documentation, reporting and billing processes that is currently not normally experienced in the publicly funded system. The working group extensively discussed whether patients should be charged for additional non-drug related costs associated with the administration of the cancer drug. Although not unanimous within the group, the majority view was that these services should be included in the payment structure and be charged to the patient.

The working group recommends that patients be charged for the acquisition cost of the drug product (no pharmacy mark-up or dispensing fee). Although there was not a unanimous opinion with respect to non-drug related costs, it was agreed that, if patients were to be charged, the amount charged should be a fixed infusion fee per visit that is reflective of the funding provided by CCO to hospitals for systemic

therapy cases/visits. Following this model, for the 2006/07 fiscal year the infusion fee charged to patients would be \$250 per visit. It was agreed that since radioimmunotherapies are significantly more complex therapies to administer, and require additional hospital resources (e.g., nuclear medicine), a fixed fee per patient be set (e.g., \$2,500 for 2006/07). The infusion fee is intended to represent costs for the other non-drug hospital services associated with providing the private drug treatment (e.g., nursing, pharmacy, laboratory, finance, etc.) In terms of other related drug costs, it is recommended that patients may be charged for the costs of additional drugs given as part of the complete drug regimen that would not otherwise be given. This could include supportive drugs or other anticancer drugs. This payment process is subject to any further direction of the Ministry of Health and Long-Term Care.

With respect to the payment process, it is recommended that hospitals seek or confirm payment prior to delivering the treatment to the patient, and that the hospital finance departments, rather than clinical staff, coordinate the billing process. It is recognized that reimbursement advice will be required for many patients interested in accessing drugs for private payment in hospitals. It is recommended that this be provided to patients through a shared service such as the CCO Cancer Drug Assistance Program (CDAP) that is currently being piloted.

Finally, it is recommended that any fee structure for provision of unfunded drugs be reviewed after the first year of implementation, and be subject to the direction of the Ministry of Health and Long-Term Care.

5. Determine the optimal approach to purchasing and dispensing consistent with professional standards to ensure patient safety

The working group specifically addressed appropriate practices concerning purchasing and dispensing in order to ensure patient safety and avoid circumstances where the integrity of the final drug product administered could be compromised. Several pharmacists were specifically engaged on this topic through a stakeholder session that informed the final working group recommendations.

The following practices are considered by the working group to be appropriate relating to drug acquisition and dispensing in order to ensure patient safety:

- Drugs should be purchased through the hospital pharmacy department.
- Drugs should be prepared, admixed and dispensed by the hospital pharmacy department, following appropriate safe-handling guidelines.
- The hospital pharmacy would be responsible for dispensing the drug to the patient.

The working group agreed that it would be inappropriate and potentially unsafe for a hospital to prepare, dispense or administer a drug that a patient had obtained from an alternate source outside of the hospital.

6. Make recommendations concerning requirements for documentation of patient care activities

Recommendations are made concerning documentation of patient care activities to ensure that appropriate data would be captured with respect to patient care and administrative data requirements to properly monitor the uptake and utilization of this service. The following recommendations are made by the working group:

- All patient care activities should be documented using usual practices according to hospital policy.
- Avoid duplication of documentation.
- Complete drug profiles and medication administration records should be maintained that include all drugs administered at the hospital (including those given for private payment).
- Volume-based activity level data should continue to be reported to CCO using the usual process, and should include data on patients who received drugs for private payment.
- A mechanism should be put into place to ensure separate reporting can be done for drugs given for private payment versus regular hospital drugs. This is a particularly important requirement to monitor and track cancer drug utilization across Ontario and determine the utilization of private payment over time.

7. Develop mechanisms (e.g., review mechanisms) to ensure consistency of application across the province

To ensure consistency of application of the recommendations, it is recommended that CCO, the Regional Cancer Programs (RCPs) and hospital boards work together to apply these recommendations in a consistent fashion in the hospitals with Integrated Cancer Programs, and to develop a plan for provision of this service within their region of the province. This might include the option that those hospitals hosting regional cancer centres be the first to take on the new policy. These are the high-volume regional hospitals and have the infrastructure to deal with these new drugs. The presence of additional points of access will certainly ensure that a range of cancer patients who were not getting these new agents will take advantage of the option to purchase these drugs.

It is also recommended that the implementation of the plan for provision of service, and the principles relating to the provision of IV cancer drugs for private payment be subject to the direction of the Ministry of Health and Long-Term Care to hospitals in Ontario.

Appendix A

Working Group Terms of Reference

Authority:

- The working group will report to Council of Academic Teaching Hospitals of Ontario (CAHO), Ontario Hospital Association (OHA), and Cancer Care Ontario (CCO) and be advisory to the Ministry of Health and Long-Term Care.

Purpose:

- To develop a recommended framework for Ontario hospitals to provide unfunded intravenously administered oncology medications to patients for private payment

Specific Deliverables:

- Agree upon a set of common principles for formulary decision-making for intravenous cancer drugs that will be funded by Ontario hospitals.
- Recommend specific criteria through which unfunded drugs should be provided for private payment to Ontario hospitals.

- Recommend a mechanism for prioritizing patients for treatment, based on availability of resources.
- Develop the payment structure for the provision of unfunded drugs (i.e., for which hospital services should the patient be charged?).
- Determine the optimal approach to purchasing and dispensing the medication to ensure that this is done consistent with professional standards to ensure patient safety, and eliminate the potential for supply chain issues.
- Make recommendations concerning requirements for documentation of patient care activities delivered for private payment in Ontario hospitals.
- Develop mechanisms (e.g., review mechanisms) to ensure consistency of application of the framework across the province.

Meetings and Timelines:

- The working group should fulfill its mandate in approximately three meetings or teleconferences.
- The work should be completed by June 2006.

Appendix B

Working Group Members

Dr. Bob Bell, University Health Network (Council of Academic Hospitals of Ontario), co-Chair

Rob Devitt, Toronto East General Hospital (Ontario Hospital Association), co-Chair

Elizabeth Carlton, Ontario Hospital Association

Flay Charbonneau, Toronto Sunnybrook Regional Cancer Centre (Pharmacist)

Greg Dorion, Ottawa Hospital Regional Cancer Centre (Program Director)

Dr. Bill Evans, Juravinski Cancer Centre (Regional Vice President)

Dr. Sheldon Fine, Carlo Fidani Peel Regional Cancer Centre (Regional Vice President)

Dr. Colin Germond, Northeastern Ontario Regional Cancer Centre (Medical Oncologist – Medical Oncology Professional Advisory Committee)

Neil Johnson, London Health Sciences Centre (Chair, Council of Academic Hospitals of Ontario, Pharmacy and Therapeutics Committee)

Mary Catherine Lindberg, Council of Academic Teaching Hospitals of Ontario (Council of Academic Hospitals of Ontario)

Shelly McKinney, Lakeridge Health Centre (Ontario College of Pharmacists)

Debbie Milliken, Cancer Care Ontario (Program Director, New Drug Funding Program)

Susan Pilatzke, Northwestern Ontario Regional Cancer Centre (Nursing)

Carol Rand, Juravinski Cancer Centre (Program Director)

Dr. Anne Smith, Cancer Centre of Southeastern Ontario (Regional Vice President)

Dr. Henry Solow, Markham Stouffville Hospital (Medical Oncologist – Medical Oncology Professional Advisory Committee)

Dr. Maureen Trudeau, Cancer Care Ontario (Provincial Head, Systemic Therapy)

Resource People to Committee*

Terry Sullivan, President and CEO, Cancer Care Ontario

Dr. Carol Sawka, Vice President, Clinical Programs, Cancer Care Ontario

Dr. Scott Berry, Joint Centre for Bioethics and Toronto Sunnybrook Regional Cancer Centre

Peter Goodhand, Canadian Cancer Society

Irene Klatt, Canadian Life and Health Insurance Association

Mary Kardos-Burton, Ministry of Health and Long-Term Care

Sandra Pellegrini, Mercer Human Resource Consulting (ECHCO)

Roz Smith, Ministry of Health and Long-Term Care

Helen Stevenson, Ministry of Health and Long-Term Care

Rino Stradiotto, Q.C., Borden Ladner Gervais LLP

* The list of resource people indicates anyone who provided input into the report.

